Tennessee Newborn Screening Program

Information Toolkit

Dried Blood Spot/Metabolic Screening
Critical Congenital Heart Disease Screening
Newborn Hearing Screening

TN Department of Health

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About This Toolkit

The purpose of this toolkit and its supplemental materials is to educate newborn screening providers on:

1. The components of the newborn screening process
2. The importance and impact of screening for each component
3. How to correctly perform and document each screen
4. To address proper shipping methods and procedures

By educating clinical staff who collect blood spots, perform pulse oximetry screens, and do newborn hearing screens, we hope to provide and encourage a standard of practice that improves the quality and timeliness of arrival of newborn screening specimens sent to the state laboratory.

Within this toolkit are various tools that include a guide for practitioners, several quick reference sheets, and other resources to be used to gain a better understanding of the newborn screening process. In addition to the printed materials located in this kit, an interactive online educational module can be found at: http://tenndepthealth.adobeconnect.com/NBSEdu/**.** There are three sections in the module: Dried Blood Spot/ Metabolic Newborn Screening, Critical Congenital Heart Disease Screening, and Newborn Hearing Screening. Each of these sections was designed to familiarize participants with the components of newborn screening following the four objectives listed above. A certificate of completion can be earned by completing all three of the sections in the module.

We encourage all individuals responsible for any area of the newborn screening process to complete the interactive online module to have a better understanding of the processes, procedures, and guidelines associated with collection. A printed toolkit is being provided for reference use within facilities, and all of the materials within the toolkit will be available in PDF format via the **Newborn Screening Webpage**. All facilities are encouraged to incorporate these materials into their new employee orientation and/or annual training.

All education materials are provided free of charge.

Tennessee Newborn Screening Program

Guide for Practitioners

Family Health and Wellness
Newborn Screening Follow-Up
Phone: 615-532-8462 *or* 1-855-202-1357
Fax: 615-532-8555
nbs.health@tn.gov

Laboratory Services
Newborn Screening Laboratory
Phone: 615-262-6300
LabNBS.Health@tn.gov

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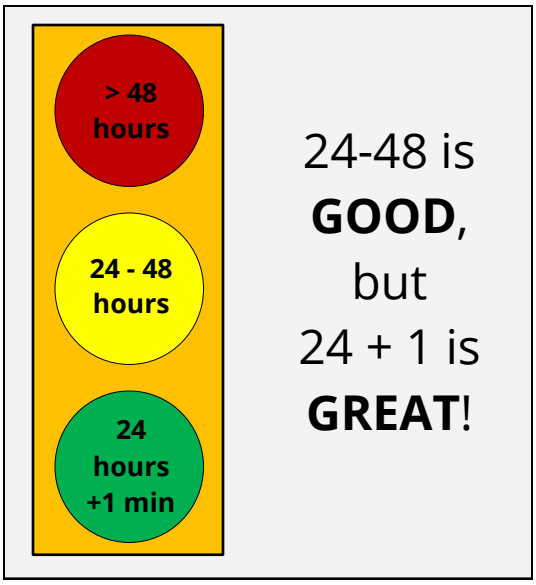
INTRODUCTION TO NEWBORN SCREENING

The Newborn Screening Program is administered by the Tennessee Department of Health with the assistance of hospitals, birthing centers, primary care providers, county health departments, cardiologists, pulmonologists, endocrinologists, audiologists, genetic and sickle cell centers from across the state. Newborn screening is a public health program designed to screen infants shortly after birth for conditions that are treatable, but not clinically evident in the newborn period. Newborn screening started in 1963 when Dr. Robert Guthrie pioneered the first screening for phenylketonuria, commonly known as PKU. The Tennessee Newborn Screening Program started in 1968 screening for PKU and now screens for many other conditions using a dried blood spot, for critical congenital heart disease (CCHD) using pulse oximetry and for congenital hearing loss via hearing screening.

METABOLIC SCREENING FROM DRIED BLOOD SPOTS

Tennessee law requires that a blood sample shall be obtained from each infant born in the state, regardless of age, before discharge from the hospital and tested for specific genetic disorders. These genetic disorders can cause mental delay or death if not treated quickly. Although most of the disorders screened for are rare, they are usually serious. Some may be life threatening; others may slow down a baby's physical development, cause intellectual disability or other problems if left untreated. The majority of the disorders being screened for cannot be cured, though they can be treated. Serious side effects can be lessened, and often completely prevented, if a special diet or other type of medical intervention is started early before the baby displays any signs of the disease.

To prevent the early effects of these disorders, the blood sample should be drawn from the infant 24 hours after birth and less than 2 days of life (24-48 hours from birth is the optimum window for sample collection though **we urge collection at 24 hours + 1 minute for increased optimization**). Infants who are screened before they are 24 hours of age must be rescreened within 24 to 48 hours by a local health department, or private physician. Infants who are born in a non-hospital setting must be taken to a hospital, local health department, or private physician between 24 and 48 hours of birth to have the blood sample collected. Drops of blood from the infant's heel are absorbed into a special filter paper attached to the Newborn Screening Form PH-1582 and sent to the Newborn Screening Laboratory at the Tennessee Department of Health (TDH) Laboratory Services.



DISORDERS

Amino Acid Disorders

Amino Acid Disorders are a group of conditions in which there is a problem with breaking down certain components of protein called amino acids. These disorders are caused by a specific defect in one of the many enzymes that perform these tasks. The specific amino acid can build up in the blood

and other organs, including the brain. This amino acid and any of its metabolites can cause serious health problems such as mental retardation, damage to vital organs, seizures or coma. The effects of the disorder will vary and depend on the age at which symptoms occur and the specific amino acid(s) elevated. Treatments vary and may include special dietary intervention, replacement medications, acute illness protocols and metabolic genetic and nutritional monitoring. Disorders include Phenylketonuria, Homocystinuria, Citrullinemia, etc.

Biotinidase Deficiency

Biotinidase Deficiency is a defect in metabolism of the vitamin biotin due to a deficiency in the activity of the biotinidase enzyme. Untreated, children have presented with seizures, skin rash, conjunctivitis, alopecia, hypotonia, ataxia, hearing loss, optic atrophy with loss of vision and developmental delays. Treatment includes oral daily biotin for life and periodic metabolic monitoring.

Congenital Adrenal Hyperplasia (CAH)

This disorder results from a deficiency of the enzyme, 21-hydroxylase, resulting in the inability of the adrenal glands to make hormones (cortisol and aldosterone) necessary to maintain life. Cortisol is responsible for maintaining the body's energy supply, blood sugar, and control of the body's reaction to stress. Aldosterone is necessary for maintaining a normal balance of salt and water in the body. An infant with the most severe form of CAH, salt wasting, may have the following symptoms within the first few weeks of life: vomiting, significant weight loss, poor feeding, lethargy, dehydration, clitoromegaly (1cm in a term infant), hypospadias, or bilateral undescended testes. Without proper treatment, an infant can go into shock and die. Females with this disorder may have ambiguous genitalia and be assigned the wrong gender at birth. Males will have no outward physical signs except possible increased pigmentation around genitals. CAH must be treated with medication and monitored by a pediatric endocrinologist.

** *In order for the test for CAH to be reported accurately it is imperative that the CURRENT weight of the infant be recorded correctly on the Newborn Screening Form.*

Congenital Hypothyroidism (CH)

Hypothyroidism occurs when the body does not produce enough thyroid hormone from the thyroid gland. This hormone is called thyroxine (T4), which is needed for brain and body growth. A decreased amount can lead to mental retardation, growth failure, deafness and other neurological problems. Some babies have presented with newborn jaundice, failure to thrive, lethargy and severe constipation. If detected early and hormone replacement is initiated, normal growth and development can take place.

Cystic Fibrosis (CF)

Cystic Fibrosis is an autosomal recessive disorder that affects the lungs and digestive system. Defective genes cause the body to produce thick mucus that clogs the lungs causing difficulty in breathing. The mucus also blocks the pancreas and stops enzymes from helping the body break down and absorb food. Symptoms can include salty tasting skin, frequent lung infections, poor growth and frequent greasy stools. Patients are treated in CF centers where there is a team of physicians, nurses,

nutritionists, respiratory therapists and social workers. CF is most common in Caucasians, but can affect all races and ethnic groups.
***Diagnostic evaluation for CF should be performed on all infants with meconium ileus regardless of the newborn screening (NBS) results because they may have low initial immunoreactive trypsinogen (IRT) values.*

Fatty Acid Oxidation Disorders

Fatty Acid Oxidation Disorders are a group of inherited metabolic conditions that lead to an accumulation of fatty acids and a decrease in cell energy metabolism due to an enzyme defect in the fatty acid metabolic pathway (use of dietary and stored fat). Crisis is usually triggered by prolonged fasting or infection. During the first crisis children have presented with metabolic acidosis, persistent vomiting, hypoglycemia, lethargy, apnea, encephalopathy, coma, cardiopulmonary arrest, or sudden unexplained death. It is imperative to identify a child with this disease so that crisis can be prevented. Treatments vary based on the specific metabolic disorder and severity of affliction. Generally, treatment consists of a specialized diet and/or replacement cofactors with close frequent metabolic monitoring and avoidance of fasting. MCAD deficiency is the most common fatty acid oxidation disorder.

Galactosemia

Infants with classical galactosemia lack an enzyme, galactose-1-phosphate uridylyltransferase (or GALT), needed to breakdown galactose, a major sugar found in milk. Due to either an absent or low GALT enzyme, galactose accumulates in the body leading to mental delay, growth deficiency, blindness, overwhelming infection and death. Infants with galactosemia can rapidly become sick after only a few days of normal feeding, and the disease can be fatal unless detected very early. Infants who are detected early are placed on a soy-based formula and a lifelong special galactose-free diet.

Hemoglobinopathies

Hemoglobin is the part of red blood cells that carries oxygen, and hemoglobinopathies are diseases that affect the kind or amount of hemoglobin a person has in the red blood cells. Some hemoglobinopathies can cause anemias or thalassemias. Hemoglobinopathies can occur in all racial groups. Sickle cell anemia is the most common hemoglobinopathy. The red blood cells are sticky and crescent or sickle-shaped and therefore do not move easily through the vascular system, decreasing the vital levels of oxygen carried throughout the body. Sickle cell anemia is common in African Americans but can also affect Caucasians and Hispanics. With screening, penicillin prophylaxis, and heightened vigilance, early death and morbidity from overwhelming sepsis are significantly decreased.

Lysosomal Storage Disorders (LSDs)

Lysosomal storage disorders are inherited disorders caused by a deficiency of specific enzymes that are normally required for the breakdown of certain complex carbohydrates or fats. If a specific lysosomal enzyme is not present in sufficient quantities, or is defective, the normal breakdown of substrates is incomplete or blocked resulting in toxic accumulation of waste in the lysosomes. This accumulation disrupts the cell's normal function and gives rise to the clinical manifestations of LSDs.

LSDs affect different body organs or systems including the skeleton, joints, eyes, heart, lungs, kidneys, skin, and frequently the central nervous system.

Organic Acid Disorders

Organic Acidemias are a group of conditions in which there is a defect in protein metabolism where an essential enzyme is absent or malfunctioning causing accumulation of organic acids in blood and urine. Clinical symptoms of Organic Acidemias may include vomiting, metabolic acidosis, ketosis, hyperammonemia, lactic acidosis, hypoglycemia, failure to thrive, hypotonia, global developmental delay, sepsis, hematological disorders and ultimately death. The effect of the disorder will depend on the age at which symptoms occur. Delay in the recognition and treatment may have tragic consequences. Treatment may include special dietary intervention, replacement medications, acute illness protocols and metabolic genetic and nutritional monitoring.

Severe Combined Immunodeficiency (SCID)

Severe Combined Immunodeficiency (SCID) includes a group of rare but serious and potentially fatal, inherited immune disorders in which T lymphocytes fail to develop and B lymphocytes are either absent or compromised. Impairment of both B and T cells leads to the term “combined.” Untreated patients develop life-threatening infections due to bacteria, viruses and fungi. Treatment may include enzyme replacement therapy, gene therapy, or hematopoietic stem cell transplant for restoration of normal immune function.

***In order for the SCID test to be reported accurately it is imperative that gestational age be recorded on the Newborn Screening Form.*

X-Adrenoleukodystrophy (X-ALD)

X-ALD is an X-linked genetic disorder and occurs when certain fats (very long chain fatty acids, or VLCFAs) cannot be broken down in the body. These fats build up and affect how the body normally functions. This disease is progressive and largely affects the nervous system and the adrenal glands. The buildup of VLCFAs may disrupt the fatty covering (myelin) of the nerve cells in the brain and spinal cord causing the fatty covering (myelin) to breakdown, which reduces the ability of the nerves to relay information to the brain. Without myelin, the nervous system cannot function properly causing for example difficulties swallowing or weakness in the legs. However, these symptoms vary depending on the type and age of onset. Treatment options include hematopoietic cell transplantation (HCT) or stem cell transplantation, corticosteroid replacement therapy, diet and other medications to relieve symptoms including stiffness and seizures.

See Appendix A for a list of all disorders screened in Tennessee.

NEWBORN HEARING SCREENING

The newborn hearing screening program began in 2001 and is responsible for assuring that all infants born in Tennessee receive a hearing screening before discharge from the hospital or prior to one month of age. The 1-3-6 plan for the newborn hearing program works to assure that: 1 - All infants will be screened for hearing loss prior to discharge or before 1 month of age. 3 - All infants who do not pass the screening will have a diagnostic audiological evaluation before 3 months of age. 6 - All infants identified with hearing loss will receive appropriate early intervention services no later than 6 months of age. AND - All families of children with hearing loss have access to parent support services.

Evidence demonstrates that when infants with hearing loss are identified in the first few months of life and receive appropriate intervention services, 80% are able to maintain age-appropriate language and speech development in the first five years of life. Communication is a time-sensitive development — if the brain is deprived of language exposure (visual or auditory) the child may have a difficult time "catching up". This could negatively impact their ability to engage with the world. Early identification of, and intervention with, children with hearing loss will increase the likelihood for success in school and life regardless of socio-economic status, communication methods, and/or gender.

CRITICAL CONGENITAL HEART DISEASE (CCHD) SCREENING

Critical congenital heart disease (CCHD) screening has been recommended nationally by the Secretary for Health and Human Services for all newborns. Pulse oximetry screening for CCHD is endorsed by the American Heart Association, American Academy of Pediatrics and American College of Cardiology. Congenital heart disease is the most common birth defect and may be detected during either the prenatal or postnatal period. Failing to detect CCHD while in the nursery may lead to serious events such as cardiogenic shock or death. Survivors who present late are at greater risk for neurologic injury and subsequent developmental delay. Early detection of CCHD can potentially improve the prognosis and decrease the mortality and morbidity rate of affected infants. Pulse oximetry has been investigated and proven to be successful in detecting some forms of CCHD in the newborn nursery.

In 2013 the state of Tennessee added pulse oximetry screening to routine testing performed on all infants. It is recommended that pulse oximetry screening be done in conjunction with other standard-of-care newborn screening such as metabolic or hearing screening. Pulse oximetry results should be documented on the Newborn Screening Form.

There are seven specific defects targeted through CCHD screening:

- Hypoplastic left heart syndrome
- Pulmonary atresia (with intact septum)
- Tetralogy of Fallot
- Total anomalous pulmonary venous return
- Transposition of the great arteries
- Tricuspid atresia
- Truncus arteriosus

TENNESSEE CODE ANNOTATED TITLE 68, HEALTH, SAFETY, AND ENVIRONMENTAL PROTECTION, CHAPTER 5 PREVENTION OF DISEASES EXCERPTS

Part 4 Newborn Testing – Metabolic Defects

68-5-401 Testing required -- Public policy.

(a)(1) The general assembly declares that, as a matter of public policy of this state and in the interest of public health, every newborn infant shall be tested for phenylketonuria, hypothyroidism, galactosemia and other metabolic/genetic defects that would result in intellectual disability or physical dysfunction as determined by the department, through rules and regulations duly promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, and that the people of this state shall be extensively informed as to the nature and effects of such defects.

Part 9 Early Detection of Hearing Loss

68-5-903 Newborn infant

Every newborn infant shall be screened for hearing loss in order to prevent the consequences of unidentified hearing loss, unless the parent or parents of the child object on the grounds that the test would conflict with the parent or parents' religious tenets or practices.

68-5-904 Child born in hospital or other specified facilities.

(1) A child born in a hospital or other birthing facility shall be screened for hearing loss prior to discharge from that facility The attending health care professional shall refer a child born in a setting other than a hospital or other "birthing" facility to the department of health or an appropriate hearing screening provider as listed in the latest edition of the directory of hearing screening providers in Tennessee for hearing screening. A child born on an emergency basis in a hospital that does not otherwise provide obstetrical or maternity services and that does not provide infant hearing screening tests prior to discharge of an infant from the hospital, shall refer a child born in that facility to the Department of Health or an appropriate hearing screening provider as listed in the latest edition of the directory of hearing screening providers in Tennessee for hearing screening. The hearing screening test shall be provided in accordance with current hearing screening standards established by a nationally recognized organization such as the Joint Committee on Infant Hearing Screening of the American Academy of Pediatrics. All screening providers or entities shall report their screening results to the Department of Health.

(2) Any medical or audiologic provider performing follow-up tests shall report the results of the tests to the Department of Health.

68-5-905 Report and referrals

The results of all hearing screenings performed pursuant to this part shall be reported to the Department of Health. The department of health shall refer any child who does not pass the hearing screening test to the Tennessee Early Intervention System (TEIS) of the Department of Education for follow-up. Children who have been identified with hearing loss or high risk conditions that place them at high risk for hearing loss as identified by standards established by a nationally recognized organization such as the Joint Committee on Infant Hearing Screening of the American Academy of Pediatrics shall be referred to the TEIS.

TENNESSEE RULES AND REGULATIONS – EXCERPTS

1200-15-1-.01 TESTS

The Department of Health will designate the prescribed effective screening tests and examinations which will be performed on newborns in accordance with Rule 1200-15-01-.02 for the detection of hearing loss, critical congenital heart disease and metabolic/genetic disorders as designated by the Department of Health.

(1) Exemptions for religious beliefs. Nothing in this part shall be construed to require the testing of or medical treatment for the minor child of any person who shall file with the Department of Health a signed, written statement that such tests or medical treatment conflict with such person's religious tenets and practices, affirmed under penalties of perjury pursuant to T.C.A. § 68-5-403. The Newborn Screening Refusal Form provided by the State should be completed, filed with the Department and retained in the medical record for the period of time defined by the hospital or provider policy.

(2) Failure to have a child tested for the detection of hearing loss and metabolic/genetic disorders as designated by the Department of Health is a Class C misdemeanor pursuant to T.C.A. § 68-5-404.

1200-15-1-.02 PERSONS AND/OR INSTITUTIONS RESPONSIBLE FOR TESTS FOR NEWBORN INFANTS

The following persons or institutions shall be responsible for hearing testing, critical congenital heart disease screening and blood specimen collection for metabolic/genetic disorders as designated by the Department of Health. Specimens and results shall be submitted in a manner as directed by the Department of Health; procedures are located on the Department's web page.

(1) Every chief administrative officer of a hospital and the attending physician in each instance shall:

a. Submit a satisfactory specimen of blood to the State Public Health Laboratory, Department of Health. This sample shall be collected between twenty-four and forty-eight (24-48) hours of age and mailed within twenty-four (24) hours of collection. In some cases it may be necessary to collect a specimen prior to twenty-four (24) hours of age if the infant is going to be discharged, transferred or transfused. (Please see page 25 for more information on the courier service provided by the lab.)

1. Recollect a specimen of blood if the infant was initially screened before twenty-four (24) hours of age. This repeat sample shall be collected between twenty-four and seventy-two (24-72) hours of age and mailed within twenty-four (24) hours of collection. If the infant has been discharged, instruct every parent, guardian, or custodian to bring the infant back to the hospital or to a physician or the nearest local health department to be re-screened.

b. Perform a physiologic hearing screen. The result of the hearing screen is to be reported to the Department of Health and should be done before hospital discharge or prior to one (1) month of age.

c. Perform pulse oximetry tests on all newborns to screen for critical congenital heart disease between twenty-four and forty-eight (24-48) hours of age. The recommended protocol for screening is available online at the Department of Health's web page.

(2) Any health care provider(s) of delivery services in a non-hospital setting shall:

a. Submit a satisfactory specimen of blood to the State Public Health Laboratory, Department of Health. This sample shall be collected between twenty-four and forty-eight (24-48) hours of age and mailed within twenty-four (24) hours of collection. In some cases it may be necessary to collect a specimen prior to twenty-four (24) hours of age if the infant is going to be discharged, transferred or transfused.
    1. Recollect a specimen of blood if the infant was initially screened before twenty-four (24) hours of age. This repeat sample shall be collected between twenty-four and seventy-two (24-72) hours of age and mailed within twenty-four (24) hours of collection. If the infant has been discharged, instruct every parent, guardian, or custodian to bring the infant back to the hospital or to a physician or the nearest local health department to be re-screened.

b. Instruct the parent, guardian or custodian to obtain a physiologic hearing screen prior to one (1) month of age. A referral may be made to the State Department of Health to assist in locating a hearing provider.

c. Perform pulse oximetry tests on all newborns to screen for critical congenital heart disease between twenty-four and forty-eight (24-48) hours of age. The recommended protocol for screening is available online at the Department of Health's web page.

(3) Any health care provider(s) of delivery services in a non-hospital setting shall:

a. Between twenty-four to forty-eight (24-48) hours of age present said infant to a primary care provider or local health department for blood specimen collection.

b. Obtain a physiologic hearing screen prior to one (1) month of age. A referral may be made to the State Department of Health to assist in locating a hearing provider.

c. Between twenty-four and forty-eight (24-48) hours of age present said infant to a primary care provider to perform pulse oximetry tests to screen for critical congenital heart disease. The recommended protocol for screening is available online at the Department of Health's web page**.**

1200-15-1-.03 NEWBORN SCREENING PAMPHLET PROVIDED TO PARENTS.

The chief administrative officer of each birthing facility shall order the distribution of a pamphlet to every parent, guardian or custodian of an infant screened. The pamphlet, distributed by the Department of Health, educates and prepares the family for newborn testing on their infant. If an infant's blood specimen was collected earlier than twenty-four (24) hours after birth and the patient is discharged home, the birthing facility must review the information on the back of the pamphlet with the family prior to discharge; the information requires the family to present the infant to the hospital, physician or health department within 24-72 hours for a repeat blood specimen. The pamphlet will have a perforated page that may be signed by the parent and placed in the medical record as documentation that the pamphlet was provided.

1200-15-1-.04 MEDICAL PROVIDERS AND LOCAL HEALTH DEPARTMENTS MUST ASSIST THE DEPARTMENT OF HEALTH.

(1) The primary care provider's responsibility is to:

a. Ensure that all newborn screening tests were conducted and provide necessary follow-up, if needed, as instructed by the Newborn Screening Program.

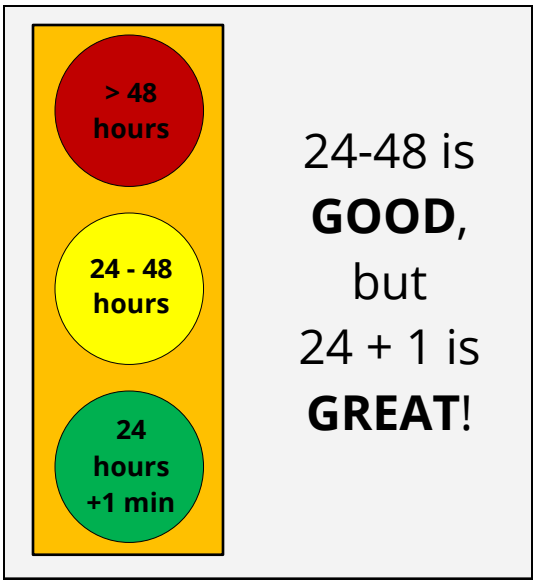
b. Recollect a blood specimen before two (2) weeks of age, as instructed by the program or tertiary center staff, or send the infant to the local Health Department for recollection.
c. Assist the Department of Health in contacting families, submitting follow-up information, making appropriate referrals and/or notifying the Department immediately if they are not the provider. The Newborn Screening Program outlines the providers' responsibilities in the practitioner guide which is available online at the Department of Health's web page.
d. Obtain further hearing tests prior to three (3) months of age if the infant did not pass the hearing screen. A referral may be made to the State Department of Health to assist in locating a hearing provider.
e. Submit the critical congenital heart disease follow-up form on infants who did not pass the pulse oximetry screen.

(2) Audiologist shall submit the hearing follow-up form on infants referred to them for further testing through the newborn screening process.
(3) Cardiologists shall submit the critical congenital heart disease follow-up form on infants referred to them through the newborn screening process.

NEWBORN SCREENING PROGRAM RESPONSIBILITIES

HOSPITAL/BIRTHING FACILITY/MIDWIFE RESPONSIBILITY

1. Completion of the Newborn Screening Form
    a. Collection forms are available from the local Health Department or the State Laboratory (615-262-6391).
    b. It is important to fill out all information on the newborn screening collection form completely and accurately. Some results are based on age, weight and/or feed status of the infant at the time of collection.
    c. Hearing Screening: It is the responsibility of the hospital to record the results of the hearing screen on the blood spot form. If the blood spot form must be sent before the hearing screen is completed, use the hearing screen form (pink tear-out form) to document hearing screen results and send separately. Be sure to indicate any applicable risk factors. NOTE: Only use the hearing screen (pink) form if hearing screen is not completed in time for the results to be documented on the blood spot form. In most cases, the hearing screen results should be documented on the blood spot form.
    d. CCHD Screening: It is the responsibility of the hospital to record the results of the CCHD screening on the blood spot form.
2. Obtain a Satisfactory Specimen
3. A satisfactory specimen is: Drops of whole blood applied evenly and allowed to soak through the filter paper and can be seen clearly with no white showing through on either side. Preferably these spots should be large enough to punch at least 11 - ⅛ inch discs with no white areas and sufficient blood remaining to perform any repeat tests as necessary.



    a. An unsatisfactory specimen of a newborn with one of the disorders can cause a possible delay in diagnosis and treatment. A specimen can be considered unsatisfactory for several reasons, including quantity insufficient; blood did not soak completely through filter paper; specimen was contaminated; or arrived in a plastic bag.
    b. Recommended techniques for obtaining a satisfactory specimen are within this document and a complete list of descriptions for unsatisfactory specimens can be found in Appendix E.
    c. Newborn screens must be collected between 24-48 hours of life and should arrive at the state lab within 2 days of collection. **TO OPTIMIZE THIS PROCESS WE ENCOURAGE THAT COLLECTION BE DONE AT 24 HOURS + 1 MINUTE OF AGE.**
4. Education:
    a. As required by the Rules and Regulations (Refer to TENNESSEE RULES AND REGULATIONS Chapter 1200-15-1-.03), the chief administrative officer of each birthing facility shall order the distribution of a pamphlet to every parent, guardian or custodian of an infant screened. The

pamphlet, distributed by the Department of Health, educates and prepares the family for newborn testing on their infant. Order forms are available online.

b. Various education tools will be provided free of charge by the Tennessee Newborn Screening Program. These include an interactive online education module that covers the three sections of newborn screening, as well as quick reference sheets and other resources. All facilities responsible for the collection of newborn screens are encouraged to incorporate these materials into their new employee orientation and/or annual training.

5. Special Care Nursery Recommendations:
    a. The "NICU" check box on the specimen card should be marked on specimens from all infants admitted to a NICU or special care nursery.
    b. Feed Status: The feeding type box should be clearly marked for "breast," "non-lactose," "TPN/lipids," "lactose," or "NPO". This information is important to Newborn Screening Laboratory staff and the baby's physician should an abnormality be detected.
        i. Soy formula or lack of milk feeding **will affect** the total galactose result.
        ii. Hyperalimentation and TPN **may affect** tandem mass spectrometry screening for some amino acid, fatty acid oxidation and organic acid disorders.
            1. If screening results suggest TPN effects, another specimen is requested when the infant has been off of TPN for at least 24 hours.
    c. Antibiotics: When infants are receiving antibiotics at the time of specimen collection, the "antibiotic" box of the specimen collection card should be marked, as the presence of antibiotics and some other medication metabolites (valproic and benzoic acids) may be detected by tandem mass spectrometry. In these cases, a repeat sample will be requested.
    d. Transfused Newborns: Always collect a newborn screening before any transfusion even if the infant is < 24 hours old. The SCID, hemoglobin and biotinidase enzyme results will be accurate and will not need to be repeated if the results are normal.
    e. Transfers: If the infant requires transfer to another facility, it is the responsibility of the birth hospital to collect a specimen prior to transfer, regardless of infant's age. If a specimen cannot be collected prior to transfer due to the medical instability of the neonate, the transferring facility is responsible for informing the admitting facility of the need for specimen collection prior to transfusion and/or within first 24-48 hours of life.
6. Quality Assurance
    a. Set up a system ensuring every infant born in your facility has had all three screens performed.
    b. Set up a system ensuring results from the state laboratory are received on all NBS specimens your facility submits.
    c. Teach new personnel the proper methods of specimen collection and review with existing personnel on a regular basis.
    d. Review monthly unsatisfactory specimen reports and take steps to lower the rate by identifying areas of weakness in your internal procedures.
    e. Reports are mailed to each birthing hospital on a monthly basis. These reports indicate the number of screens performed during the specified time period, the unsatisfactory specimen rate, age at collection, and transit time rates for date of collection range. Monitor these

reports and take steps to decrease the number of unsatisfactory specimens submitted and ensure screens are being performed.

7. Special circumstances:
    a. Early Discharge: If the infant is to be discharged at less than 24 hours of age, collect specimen prior to discharge. Inform parents that infant must be rescreened between twenty-four and seventy-two (24-72) hours of age.
    b. Adoption Cases: If a specimen needs to be repeated, a letter will be sent using the information listed on the form. Do not put birth mother's information on the form; list either adoptive parents, adoption agency, or lawyer. Also write ADOPTION CASE on the collection form.
    c. Refusal of Test by Parent: If a parent refuses the initial Newborn Screen, they should sign the Newborn Screening Refusal Form (PH-3686) designated by the State Newborn Screening Program. Retain a copy in the medical record and attach the completed refusal form to the newborn screening filter card form (without blood) which should have the following information: marked Refused as reason for NO BLOOD SCREEN; attach refusal form; infant's first and last name; infant's date of birth and time of birth; birth hospital ID; mother's first and last name; and, mother's address, city, state and zip. If parents also refuse the hearing screen and CCHD screen, please mark as appropriate in those boxes at the bottom of the newborn screening filter card.
    d. Death of a Newborn:
        i. If a screen was collected and a newborn has died, notify the Newborn Screening Follow-Up program by fax (615-532-8555) as soon as possible. Include the child's name, birth date, mother's name and the date of death. Follow-up will close the case so mother will not receive letters requesting a repeat specimen if needed.
        ii. If you are the facility/individual responsible for collecting the initial newborn screen and you did not because the infant died, please complete the newborn screening filter card form (without blood) which should have the following information: marked Expired as reason for NO BLOOD SCREEN; date of death; infant's first and last name; infant's date of birth and time of birth; birth hospital ID; mother's first and last name; and, mother's address, city, state and zip.

STATE LABORATORY RESPONSIBILITY

The Laboratory performs tests on all specimens, reports the results to both the provider and to the hospital of collection listed on the NBS form. Presumptive positives for diseases are immediately reported to the follow-up program.

1. Test Methods
    a. Galactosemia testing is performed by a quantitative enzymatic fluorometric method to detect Uridyl transferase enzyme activity and Total Galactose.
    b. Biotinidase screening is performed by colorimetric methodology. It is a semi-quantitative analysis for the determination of Biotinidase activity in dried whole blood spots.
    c. Thyroid testing is performed by a quantitative fluoroimmunoassay (FIA) method which detects the amount of thyroid stimulating hormone (TSH) present.
    d. Hemoglobin testing is performed by High Performance Liquid Chromatography (HPLC).

e. Congenital adrenal hyperplasia employs a quantitative fluoroimmunoassay (FIA) methodology, which detects the amount of 17α-hydroxyprogesterone (17-αOHP).
f. Organic Acid, Fatty Acid and Amino Acid tests are analyzed quantitatively by Tandem Mass Spectrometry. These analytes are detected by their mass to charge ratio.
g. Cystic Fibrosis testing is performed by a quantitative fluoroimmunoassay (FIA) method which detects the amount of Immunoreactive Trypsinogen (IRT) present. Specimens with elevated IRT are tested for mutations using a 39 CFTR mutation panel.
h. Severe Combined Immunodeficiency (SCID) testing is performed using a real-time PCR method which detects T-cell receptor excision circles (TREC).
i. Lysosomal storage disorders (LSDs): Enzyme activity is assessed by measuring the product generated when an enzyme reacts with a synthetic substrate to create a specific product. Enzyme activity is analyzed by Tandem Mass Spectrometry with comparison to internal standards, and enzyme activities are express as micromoles (µmol) per hour (h) per Liter (L).
j. X-Adrenoleukodystrophy testing is analyzed quantitatively by Tandem Mass Spectrometry. These analytes are detected by their mass to charge ratio.

2. Specimens within Normal Limits (WNL):
    a. Reports of normal specimens are mailed within 5-7 working days from receipt of specimen to provider and hospital of collection listed on the Newborn Screening Form. No follow-up is needed, although providers are responsible for making sure their patient has had a newborn screen, and for reviewing and interpreting results with respect to blood transfusion and diet status.
3. Unsatisfactory Specimens:
    a. Medical technologists closely examine each specimen for quality and quantity before performing tests. There are several reasons a specimen might be marked unsatisfactory. Some of the more common reasons are: quantity not sufficient, the blood spots did not uniformly soak through the filter paper, the specimen was too old by the time it arrived in the state lab or the baby was <24 hours of age when collected.
    b. When a specimen is identified as unsatisfactory, the lab notifies the provider and hospital of collection by mail the next working day. All unsatisfactory specimens are tested, even though the integrity of the specimen is in question, and if a positive, or suspected positive, is found, results are communicated to the provider so that treatment can be initiated. However, all unsatisfactory specimens are reported as unsatisfactory and must be repeated.
    c. See Appendix E for a description of common causes of unsatisfactory specimens.
4. Process for Presumptive Positive for Disease:
    a. The laboratory reports a presumptive positive result, by phone/email, to the follow-up program as soon as it has been determined, generally within 24-48 hours after the specimen is received. Results will also be mailed to the provider and hospital of collection when other tests are completed, within 5-7 days from receipt of specimen.

PEDIATRIC CASE MANAGEMENT AND FOLLOW-UP RESPONSIBILITY

The Follow-Up Program informs the parent and provider by mail of the need for a repeat specimen due to abnormal values, unsatisfactory specimen, transfusion, specimen collected at <24 hours of age or possible hemoglobin trait. It is the responsibility of the parents and provider once notified to obtain a repeat specimen.

1. Unsatisfactory Specimens:
    a. If results are unsatisfactory (poor collection) both the provider and parents will receive a letter from the Newborn Screening Follow-Up program requesting a repeat specimen to be submitted. It is the responsibility of the parents and provider once notified to obtain a repeat specimen. Specimens are mailed to the state laboratory; a second unsatisfactory specimen at this point can cause a costly delay in diagnosis and treatment.
2. Process for Presumptive Positive for Disease:
    a. If the results are abnormal and show a possible disease, follow-up notifies the provider and tertiary center (i.e., endocrinology, genetic, pulmonology or sickle cell center) by phone and fax. Appropriate recommendations are made based on the result. Follow-up staff ensures that confirmatory testing, diagnosis and treatment are initiated when necessary.
    b. Remember, this is a screening program and further testing will need to be performed prior to diagnosis and treatment.
3. Quality Assurance:
    a. Weekly and monthly reports are sent to each birthing facility in the state. These reports indicate the number of screens performed during the specified time period, the unsatisfactory specimen rate, age at collection, and specimen transit time rates.
    b. The state goals for each indicator are as follows: 100% of infants to have screens performed; <1% unsatisfactory rate; all specimens collected between 24-48 hours of age; and, specimen arrival to lab <2 days from collection.
4. Education:
    a. Newborn screening submitters/providers will have access to online education modules for all staff responsible for the collection of screening samples. In addition, each birthing facility will be provided with a printed education toolkit that contains a copy of the Guide for Practitioners as well as several reference guides. These print materials will also be available online for printing.
    b. Facilities are encouraged to incorporate the educational materials provided into their new employee orientation and/or annual training. Follow-up staff will perform site visits to provide hands-on assistance, if needed, based on Quality Assurance reporting.

PRIMARY CARE PROVIDER RESPONSIBILITY

It is the provider's responsibility to make sure the newborn has had a screen, and has reviewed and interpreted results with respect to blood transfusion and diet status. Also providers should inform parents of results. If a specimen is unsatisfactory or abnormal, it is the responsibility of parents and providers to obtain a repeat specimen once notified. The screening results will be mailed to the submitter of the specimen and to the provider listed on the Newborn Screening Form.

1. Keep in mind; this is a SCREEN, not a diagnostic test:

   a. The newborn screening test can be affected by baby's age; medical or treatment status at the time of specimen collection; the quality and quantity of the specimen or other variables. The newborn screening test may not detect all affected babies.
   b. The possibility of false negative or false positive results must always be considered when screening newborns for disorders. Regardless of NBS results, diagnostic evaluation should be performed on an infant presenting with clinical symptoms.
2. Unable to locate:
   a. When follow-up and/or the physician are unable to contact or locate an infant for repeat testing due to unsatisfactory or abnormal results, the local health department should be contacted to assist.
3. Secure Remote Viewer (SRV):
   a. Secure Remote Viewer (SRV) is a web based application which will allow you to view digital copies of the patient result reports. Healthcare providers must be registered with the Department of Health in order to gain access to the SRV.
   b. If you would like access to the system, please fill out the SRV Access Form at: http://health.state.tn.us/MCH/NBS/PDFs/PH 3909.pdf and FAX it to (615) 532- 8555.

REQUESTING EDUCATION MATERIALS AND FORMS

ONLINE EDUCATION FOR PRACTITIONERS

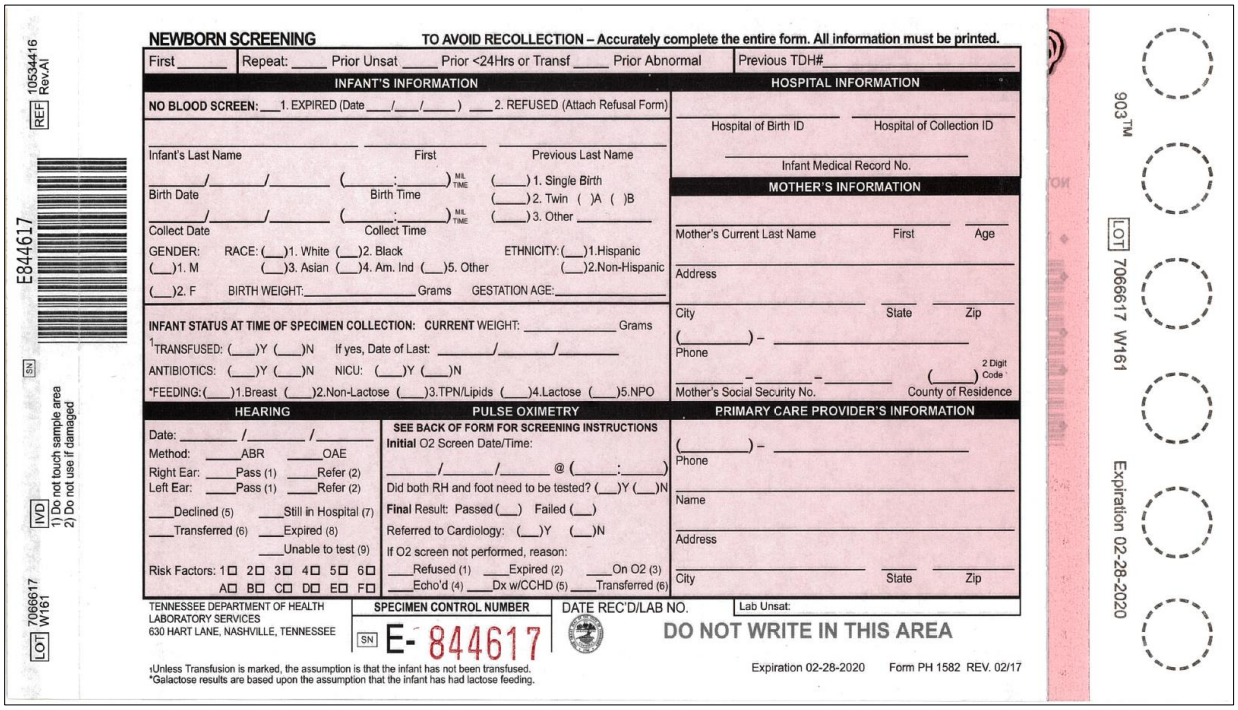
An interactive, self-paced, web-based training module that addresses proper specimen collection, processing, and transport is available at: http://tenndepthealth.adobeconnect.com/NBSEdu/. There are 3 sections: Dried blood-spot/Metabolic, Critical Congenital Heart Disease, and Newborn Hearing Screening. A certificate of completion can be earned by completing all three of the sections in the training module, and supplemental educational materials can be found on the newborn screening webpage. These materials address key points in specimen collection and processing and can be printed to be used as quick reference tools if needed. The web-based training module and resource materials are available to all practitioners who play a role in the collection and/or follow-up processes. Hospitals are encouraged to incorporate the educational materials provided into their new employee orientation and/or annual training.

PARENT EDUCATION AND PAMPHLETS

As required by the Rules and Regulations (Refer to TENNESSEE RULES AND REGULATIONS Chapter 1200-15-1-.03), the chief administrative officer of each birthing facility shall order the distribution of a pamphlet to every parent, guardian or custodian of an infant screened. The pamphlet, distributed by the Department of Health, educates and prepares the family for newborn testing on their infant. Order forms are available online.

NEWBORN SCREENING COLLECTION FORMS

Use the Newborn Screening Collection Form PH-1582. Forms are available from your local county health department and health departments can order more forms from the Shipping Department of Laboratory Services (615-262-6391).



NEWBORN SCREENING — TO AVOID RECOLLECTION – Accurately complete the entire form. All information must be printed.

First _____ | Repeat: ____ Prior Unsat ____ Prior <24Hrs or Transf ____ Prior Abnormal | Previous TDH#_____

INFANT'S INFORMATION

NO BLOOD SCREEN: ___1. EXPIRED (Date ___/___/____) ___2. REFUSED (Attach Refusal Form)

Infant's Last Name | First | Previous Last Name

Birth Date | Birth Time (MIL TIME) | (____) 1. Single Birth (____) 2. Twin ( )A ( )B (____) 3. Other _____

Collect Date | Collect Time (MIL TIME)

GENDER: (___)1. M (___)2. F

RACE: (___)1. White (___)2. Black (___)3. Asian (___)4. Am. Ind (___)5. Other

ETHNICITY: (___)1.Hispanic (___)2.Non-Hispanic

BIRTH WEIGHT:_____Grams GESTATION AGE:_____

INFANT STATUS AT TIME OF SPECIMEN COLLECTION: CURRENT WEIGHT: _____ Grams

[1]TRANSFUSED: (___)Y (___)N If yes, Date of Last: ___/___/___

ANTIBIOTICS: (___)Y (___)N NICU: (___)Y (___)N

*FEEDING: (___)1.Breast (___)2.Non-Lactose (___)3.TPN/Lipids (___)4.Lactose (___)5.NPO

HOSPITAL INFORMATION

Hospital of Birth ID | Hospital of Collection ID

Infant Medical Record No.

MOTHER'S INFORMATION

Mother's Current Last Name | First | Age

Address

City | State | Zip

(____) – Phone

Mother's Social Security No. | (____) 2 Digit Code County of Residence

HEARING

Date: ___/___/___

Method: ____ABR ____OAE

Right Ear: ____Pass (1) ____Refer (2)

Left Ear: ____Pass (1) ____Refer (2)

____Declined (5) ____Still in Hospital (7)

____Transferred (6) ____Expired (8)

____Unable to test (9)

Risk Factors: 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ A☐ B☐ C☐ D☐ E☐ F☐

PULSE OXIMETRY

SEE BACK OF FORM FOR SCREENING INSTRUCTIONS

Initial O2 Screen Date/Time:

___/___/___ @ (____:____)

Did both RH and foot need to be tested? (___)Y (___)N

Final Result: Passed (___) Failed (___)

Referred to Cardiology: (___)Y (___)N

If O2 screen not performed, reason:

____Refused (1) ____Expired (2) ____On O2 (3)

____Echo'd (4) ____Dx w/CCHD (5) ____Transferred (6)

PRIMARY CARE PROVIDER'S INFORMATION

(____) – Phone

Name

Address

City | State | Zip

TENNESSEE DEPARTMENT OF HEALTH
LABORATORY SERVICES
630 HART LANE, NASHVILLE, TENNESSEE

SPECIMEN CONTROL NUMBER: SN E- 844617

DATE REC'D/LAB NO.

Lab Unsat:

DO NOT WRITE IN THIS AREA

[1]Unless Transfusion is marked, the assumption is that the infant has not been transfused.
*Galactose results are based upon the assumption that the infant has had lactose feeding.

Expiration 02-28-2020 Form PH 1582 REV. 02/17

REF 10534416 Rev.AI

E844617 SN

IVD 1) Do not touch sample area 2) Do not use if damaged

LOT 7066617 W161

903™

LOT 7066617 W161

Expiration 02-28-2020

Filter paper specimen cards should be stored in a cool, dry location out of direct sunlight. Cards should be stored in their original wrappings and stacked in a manner that avoids compressing the paper. Each card has a printed expiration date and once expired, the specimen cannot be considered valid. The expiration date of the filter paper is printed near the bottom right corner of the form. It will have the year-month. Forms are good until the last day of the month printed on the form for the year specified. (Example: EXP. 01-2017 means do not use the form after 01/31/2017.) Blood collected on forms after the expiration date will be reported out as "Unsatisfactory Filter Paper Expired" and another specimen will have to be submitted.

TOP OF FORM

- **First ____:** If this is the "First" specimen ever collected on the infant, place a mark on the "First" line. If the specimen is marked as a "First" all tests are automatically performed.
- **Repeat: ____Prior Unsat ____Prior<24 hrs or Transf____Prior Abnormal____:** If this is a repeat specimen and the provider or the parent was sent a letter indicating that the specimen should be repeated, a reason would be given on the letter. If the specimen was unsatisfactory for any reason and this is why the repeat is being done place a mark on the "Prior Unsat" line. If the first specimen was collected before the infant was 24 hours of age and this is why the repeat is being done or if the specimen was collected after the infant was transfused and this is why the repeat is being done, place a mark on the "Prior Abnormal" line.

- **Previous TDH#:** If this is a repeat specimen and the provider or the parent was sent a letter indicating that the specimen should be repeated, write the 11 digit unique TDH number included in the letter in this space. If possible enclose a copy of the letter with the repeat specimen.

INFANT'S INFORMATION

- **Infant's Last Name:** Legibly print the infant's last name.
- **Infant's First Name:** If the infant has a first name, print it legibly here. If the infant does not have a first name at the time of collection and it was a single birth, write "BOY" for the first name if it is a male infant or "GIRL" for the first name if it is a female infant. *If there are multiple births, also indicate the birth order by using A, B, C, etc.*
  EXAMPLE: GIRL "A", BOY "B", GIRL "C", BOY "D".
- **Previous Last Name:** If the infant has had a change in their last name, legibly print their previous last name here. This is very important! Without this information we are unable to identify when an infant has had a repeat specimen collected.
- **Birth Date:** The day the infant was born. Write the date as MM / DD / YY. The date should be the same day as recorded on the infant's birth certificate.
- **Birth Time:** The time the infant was born in military time (See Appendix B for a military time conversion chart).
  EXAMPLE: WRITE 3:00AM AS 0300 AND 3:00PM AS 1500. The use of strict military time will indicate AM or PM. The time should be the same time as recorded on the infant's birth certificate.
- **Collect Date:** This is the date the specimen was collected. Write the date as MM / DD / YY.
- **Collect Time:** The time the specimen was collected in military time.
- **Single Birth:** If the infant was a single birth, mark (__) 1. Single Birth.
- **Twin (_)A (_)B:** If the infants were twins mark (__) 2. Twin and mark either (_) A for the first born or (_) B for the second born.
- **Other:** If the delivery is triplets (or more), mark (__) 3. Other followed by the number and letter to indicate the birth order. EXAMPLE: Triplets would be written as 3A, 3B and 3C. Quadruplets would be written as 4A, 4B, 4C and 4D.
- **Gender:** If the infant is a boy mark (_) 1. M and if the infant is a girl mark (_) 2. F.
- **Race:** Place a mark next to the category of race for the infant (_) 1. White, (_) 2. Black, (_) 3. Asian, (_), 4. Am. Ind, (_) 5. Other.
- **Ethnicity:** Place a mark next to the category for the ethnicity of the infant (_) 1. Hispanic or (_) 2. Non-Hispanic.
- **Birth Weight:** Give the weight of the infant at birth in grams. (See Appendix C for a pounds and ounces to grams conversion chart).
- **Gestation Age:** Indicate in weeks the age of infant at time of birth. EXAMPLE: 39 4/7, 39.4.

STATUS OF THE INFANT AT TIME OF COLLECTION

- **Current Weight:** Give the weight of the infant at the time the specimen was collected in grams. ***The current weight of the infant must be recorded accurately so the CAH test results are accurate.*
- **Transfused:** If the infant was not transfused mark (_) No. If the infant was transfused, in utero or after delivery, mark (_) Yes and then enter the date of last transfusion (MM / DD / YY) prior to the specimen

being collected. ***The transfusion information must be recorded accurately so results are reported accurately.*

- **Antibiotics:** If the infant has had antibiotics prior to specimen collection, mark (_) Yes; otherwise mark (_) No.
- **NICU:** If the infant is in the NICU at the time of collection mark (_) Yes; otherwise mark (_) No.
- **Feeding:** Place a mark next to the method by which the infant is currently being fed (_) 1. Breast, (_) 2. Non-Lactose, (_) 3. TPN/Lipids, (_) 4. Lactose, (_) 5. NPO.
  ***If the baby has received TPN within 24 hours of collecting the filter paper this can affect amino acid results.*

HOSPITAL INFORMATION ***A lab report will be mailed to the hospital of collection*.

- **Hospital of Birth ID and Hospital Collected ID**: Enter the seven-digit hospital code that indicates both the location of the infant's birth and of the collection hospital. The hospital code is available from the hospital of birth (See Appendix G for a list of Tennessee Birthing Facility codes). *This blank must be completed regardless of the provider.* If the infant has been transferred, the hospital of collection may be different from the hospital of birth. If the infant was not born in a Tennessee hospital, indicate the location by giving the name and location of the hospital of birth. If the infant was not born in a hospital, enter the two-digit code for the county and record "HOME" in hospital block (See Appendix D for a Tennessee county code list).
- **Medical Record Number:** Give the unique patient number assigned to the infant in the hospital.

MOTHER'S INFORMATION

- **Adoption:** If a newborn has been adopted please write "ADOPTION CASE" on the form and put either the adoptive parents or the adoption agency's information in the spaces under Mother's Information. If a repeat specimen is required, letters will be sent to the mother listed on the form until the Newborn Screening Laboratory receives a repeat specimen. We do not want to send letters to the birth mother.
- **Mother's Current Last Name, First Name, Age:** Legibly print the mother's legal last name, first name, and age at the time of the infant's birth.
- **Address, City, State, Zip Code:** Legibly print the mother's complete address where she is currently living including the city, state and zip code. ***If the mother's residence is not in the USA, name the country.*
- **Phone Number:** Legibly print the area code and home phone number where the infant's mother can be contacted. If the mother does not have a phone, give the area code and phone number of a relative or neighbor who could easily contact the mother in case of an abnormal result.
- **Mother's Social Security No.:** Legibly print the mother's social security number (this field is optional).
- **County of Residence:** Legibly print the two-digit code that corresponds to the county in which the mother resides. (See Appendix D for a Tennessee county code list)

PRIMARY CARE PROVIDER'S INFORMATION *** A lab report will be mailed to the Physician or Provider listed here.*

- **Phone:** Legibly print the area code and phone number of the physician or health care provider to be contacted if there is an abnormal test result.
- **Name:** Legibly print the first and last name of the physician or heath care provider.

- **Address, City, State and Zip Code:** Legibly print the complete street address, city, state and zip code of the physician or health care provider.

HEARING

- **Method:** Place a mark next to _ABR if the infant was tested by the Auditory Brainstem Response (ABR) or Automated Auditory Brainstem Response (AABR) method. Place a mark next to _OAE if the infant was tested by the Otoacoustic Emissions (OAE) using the Distortion Product Otoacoustic Emissions (DPOAE) or the Transient Evoked Otoacoustic Emissions (TEOAE) method. If both methods were used, mark the method administered prior to discharge and the results.
- **Right Ear, Left Ear:** Place a mark next to _Pass 1 or _Refer 2 for both left and right ear depending on results. Pass is the term used for a test that indicates the hearing is within normal limits. Refer is the term used for referral of infants for further evaluation.
- If the hearing test was not performed please indicate the reason by marking one of the following:
- __Declined (5), __Transferred (6), __Still in Hospital (7), __Expired (8), __Unable to test (9)
  ***If declined, attach a refusal form signed by the parent/s*
- **Risk Factors:** Indicate risk factors by marking the appropriate box. See the back of the Hearing screening copy of the Newborn Screening Form for a description of Risk Indicators for Hearing Loss.

PULSE OXIMETRY

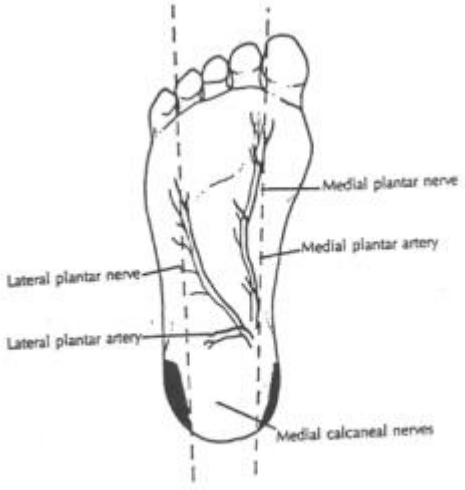
- **Initial O2 Screen Date/Time:** Indicate date, MM/DD/YY, and time the test was conducted. (See Appendix B for a military time conversion chart).
- Did both right hand (RH) and foot need to be tested?: Answer by marking either (_)Y or (_)N.
- **Final Result:** Indicate the results of the test by either marking Passed(_) or Failed(_).
- **Referred to Cardiology:** Indicate by marking either (_)Y or (_)N.
- **If not performed, reason:** Indicate if the test was not performed by marking __Refused (1), __Expired (2), or __On O2 (3), __Echo'd (4), __Dx w/CCHD (5), __Transferred (6).
  ***If refused, attach a refusal form signed by the parent/s.*

SCREENING PROCESS

BLOOD SPOT COLLECTION PROCESS

You will need the following materials to perform the heel stick procedure for the collection of the dried blood spots:

- Newborn screening card
- Powder-free gloves
- Alcohol wipes
- Lancet
- Sterile gauze



Verify the patient information on the specimen collection form with the infant's identification band and appropriate chart records before sticking the infant. Check the expiration date of the form. If it has expired do not use it. Appropriate biohazard precautions should be used. Wear powder free-gloves and change gloves between infants. Never reuse lancets; place them in a puncture proof sharps container after use. Place biohazardous material in appropriate containers.

Follow facility handwashing protocol and put on a pair of powder-free gloves. Then proceed to select an appropriate puncture site on the infant's heel. The shaded areas on the image to the right indicate the preferred areas for puncture. Guidance is also provided on the back of the collection form. Next, place the infant's legs lower than its heart to increase venous pressure and enhance blood flow. Warm the site with a warm, moist cloth for 3 to 5 minutes to increase blood flow.

Cleanse the site with a hospital approved antiseptic, and then wipe it dry with sterile gauze. Residual antiseptic (e.g., alcohol) can contaminate the blood specimen making it unsatisfactory. Puncture the heel with a sterile automated lancet. Be sure to use an appropriate sized lancet, and make sure to press the lancet firmly against the skin prior to activating the device. Wipe away the first drop of blood with a sterile gauze pad. This first drop could contain tissue fluid that could contaminate or dilute the specimen.

Allow another large drop of blood to form; it should be large enough to soak into the filter paper to completely fill the circle. Lightly touch the filter paper to the large drop of blood as close to the center of the circle as possible. Be careful not to touch the infant's skin, allowing the drop of blood to expand within the circle and soak through to the other side. *Apply the blood to only the front side of the filter paper and DO NOT use more than one blood drop per circle.*

Fill in all the remaining circles. Use very gentle, intermittent pressure to the area surrounding the puncture site. Do not milk or squeeze the area because it could create serum rings that lead to unreliable results. It is permissible for the blood to go outside the circles lines, but do not allow it to overlap on blood in an adjacent

circle. Do not use capillary tubes or syringes to fill circles. Recollect immediately if tiny blood clots appear on the specimen or if any fluid or substance contaminates the specimen.

Once the blood collection is completed, hold the infant's foot above the heart level and press a sterile gauze to the puncture site until the bleeding has stopped. Air-dry the blood specimen horizontally at room temperature away from heat or direct sunlight for at least 3 hours. Do not allow the blood spots to touch any surface. Do not close the fold-over-paper protective flap for at least 3 hours and the specimen is completely dry.

HEARING SCREENING PROCESS

Using Combined Otoacoustic Emission (OAE): First, using one hand, gently pull back on the outer ear and with the other lay the probe aiming it toward the ear canal and gently push forward. Ensure that the baby and the screener are positioned in a way that the ear canal is visible. Also, place the cable out of the way, so it cannot easily be knocked out due to movement. Massage or pull back gently on the ear to make sure the canal is open and that the correct size probe tip has been chosen for use. It should be slightly larger than the opening of the baby's ear canal to reduce any background noise. Conduct the OAE without holding the probe in place during the screening. Once this process is complete, check that the probe is clean of debris, and screen the opposite ear.

Using Automated Auditory Brainstem Response (ABR): Similarly to the steps in the use of OAE use one hand to pull back on the outer ear and with the other lay the probe aiming it toward the ear canal and gently push forward. Complete this step for both ears before making sure that the cable is placed out of the way so it cannot easily be knocked out due to movement. Massage or pull the ear to make sure that the ear canal is open, and conduct the ABR. Do not hold the probe in place during the screening.

Interpreting Results

With use of either equipment type, at the completion of the screening, the equipment will display PASS or REFER results for each ear screened. Be sure to record all data as outlined on the newborn screening collection form. If an initial test is reported as a "REFER" and sent in with the blood spot before a follow-up screen is done, AND the infant "PASSES" a follow-up screen completed prior to discharge, the rescreen may be reported on the pink tear out copy or on a "Hearing Screening Only" form.

CCHD PULSE OXIMETRY SCREENING PROCESS

It is important to conduct pulse oximetry screening in a quiet area and, if possible, with a parent present to soothe and comfort the infant. If possible, conduct screening while the infant is awake and quiet. Do not attempt to perform this screen on an infant while he or she is crying or cold. Be sure to use a pulse oximeter that has been approved by the FDA for use on neonates, and have a backup sensor if using a reusable one.

The best places to perform pulse oximetry on an infant are around the palm and foot. The finger is not a good place for newborns due to their small size. The photodetector portion of the probe should be placed on the fleshy portion of the outside of the infant's hand or foot, depending on algorithm protocol. Place the light emitter portion of the probe on the top of the hand or foot with the photodetector directly opposite of light emitter.

Interpreting Results

There are three basic categories: an automatic fail; an automatic pass; or, a fail that requires further action. The protocol in Tennessee is unique in that the algorithm (See Appendix F) used instructs to start with screening ONLY a foot first. The first step is to screen either foot.

- If 97 - 100%: Mark *PASSED* on form. No further testing needed.
- If <90%: Mark *FAILED* on the form.
- If 90-96%: Add the screening of right hand.
    - If both the right hand and foot need to be screened, note it on the collection form in the indicated space, and proceed using the protocol.
    - Mark *PASSED* if:
        - ≥95% in either extremity with a ≤3% difference between the right hand and foot
    - Mark *FAILED* if:
        - <90% in either the right hand or the foot at any time
        - <95% in both the right hand and the foot, or a >3% difference between right hand and foot on three measurements each separated by an hour.

A newborn with a failed screening should be referred for clinical assessment. Only indicate "Referred to Cardiology" in the instance that a baby was referred after clinical assessment.

Remember that a "PASS" does not exclude the existence of a cardiac disorder! If cardiac evaluation is otherwise indicated (e.g., clinical signs, prenatal diagnosis of critical congenital heart disease, dysmorphic features, etc.), proceed with cardiac evaluation ***even if*** the baby receives a pass on the pulse oximetry screen. If the results are "FAIL", it means that the baby's test results showed low levels of oxygen in the blood, which can be a sign of a CCHD. This does not always mean that the baby has a CCHD. It just means that more testing is needed.

SHIPPING SPECIMENS TO LABORATORY SERVICES

Newborn screening disorders are serious and can be life threatening, therefore early detection and treatment is vital. Failure to submit specimens promptly may unnecessarily delay detection and treatment of affected infants.

Currently, all Tennessee **birthing hospitals** may utilize the Department supported courier service for pickup of newborn screening specimens and shipment to the Nashville Newborn Screening Laboratory. Contact the Newborn Screening Program for more information about this service by email or phone at LabNBS.Health@tn.gov or 615-262-6300.

1. After allowing the specimen to dry completely for at least 3 hours, ensure that it is completely dry.
2. All efforts should be made to ensure that specimens are shipped within 24 hours of their collection.
3. Ensure that the protective flap is closed over the top of the blood spots. *DO NOT tape the flap or fold the form.* The biohazard label should be placed on the outside of the flap of the form.
4. Place the form in a paper envelope labeled: “Dried Clinical Specimen” and *attach a red, Nashville courier label* onto the shipping envelope. Be sure to write in a return address or place a return address label.
5. If you are sending more than one form, rotate the forms 180° so that the blood-spots are not stacked directly over one another, but are alternated.
6. Specimens are now ready for shipment and should be taken to the designated pickup location within your facility. Make sure you take the time to locate your facility’s pickup location and to find out the time of your daily courier pickups.
7. If there are questions regarding where to take your specimens for shipment or what time the courier arrives at your location, please contact your hospital administration.
8. Important shipment reminders:
    a. Do not bundle or hold specimens to ship multiple days at one time.
    b. Do not ship specimens in a plastic or biohazard bag. This can alter components of the blood and/or enzyme activity.
    c. Do not expose specimens to extreme temperatures or humidity.
    d. Specimens will be considered unsatisfactory if they are received more than 10 days after collection.

Appendix

NEWBORN SCREENING DISORDERS

AA (Amino Acid)/ E (Endocrine)/ F (Fatty)/ Hb (Hemoglobin)/ O (Organic)

Disorders by MS/MS	OMIM	CODE	
2 Methyl 3 hydroxy butyric aciduria	**300256**	2M3HBA	O
2 Methylbutyryl Glycinuria	**610006**	2MBG	O
2,4 Dienyl CoA Reductase Deficiency	**222745**	DE RED	F
3 Hydroxy 3 Methylglutaric Aciduria	**246450**	HMG	O
3 Methyl Crotonyl CoA Carboxylase Deficiency	**210200**	3-MCC	O
3 Methylglutaconic Aciduria	**250950**	3MGA	O
Argininemia	**207800**	ARG	AA
Argininosuccinic Aciduria	**207900**	ASA	AA
β Ketothiolase Deficiency (aka SKAT)	**607809**	βK	O
Carbamoyl Phosphate Synthetase I Deficiency	**237300**	CPS I	AA
Carnitine Palmitoyltransferase Type I Deficiency	**600528**	CPT IA	F
Carnitine Palmitoyltransferase Type II Deficiency	**600650**	CPT II	F
Carnitine Acylcarnitine Translocase Deficiency	**212138**	CACT	F
Carnitine Uptake Defect	**212140**	CUD	F
Citrullinemia Type I (Classic - Arginosuccinate Synthetase Deficiency) Type II (Citrin Deficiency)	 **215700** **605814**	 CIT CIT II	AA
Glutaric Acidemia Type I	**231670**	GA1	O
Glutaric Acidemia Type II (aka Multiple AcylCoA Dehydrogenase Def)	**231680**	GA2	F
Homocystinuria	**236200**	HCY	AA
Hypermethioninemia due to Glycine N-Methyltransferase Deficiency due to S-Adenosylhomocysteine Hydrolase Deficiency due to Methionine Adenosyltransferase Deficiency	 **606664** **180960** **250850**	MET	AA
Hyperornithinemia Hyperornithinemia -Hyperammonemia-Homocitrullinuria with Gyrate Atrophy	 **238970** **258870**	HyperOrn (includes HHH)	AA
Hyperphenylalaninemia due to Phenylalanine Hydroxylase Deficiency due to GTP Cyclohydrolase I Deficiency due to Pterin-4-Alpha-Carbinolamine Dehydratase Deficiency due to 6-Pyruvoyltetrahydropterin Deficiency Defects of biopterin co factor biosynthesis Defects of biopterin co factor regeneration	 **261600** **233910** **264070** **261640** **261630** **182125**	 H-PHE BIOPT (BS) BIOPT(REG)	 AA
Isobutyrylglycinuria	**611283**	IBG	O
Isovaleric Acidemia	**243500**	IVA	O
Long Chain L-3 Hydroxylacyl-CoA Dehydrogenase Def.	**609016**	LCHAD	F

Disorders by MS/MS	OMIM	CODE	
Lysosomal Storage Disorders			
Fabry Disease	**301500**	GLA	--
Gaucher Disease	**230800**	GBA	
Krabbe Disease	**245200**	GALC	
Pompe Disease	**232300**	GAA	
Mucopolysaccharidosis type I (MPS I)	**607014**	IDUA	
Malonic Acidemia	**606761**	MAL	O
Maple Syrup Urine Disease	**248600**	MSUD	AA
Medium Chain AcylCoA Dehydrogenase Deficiency	**607008**	MCAD	F
Medium/Short chain L-3 hydroxyacyl CoA dehydrogenase Def.	**601609**	M/SCHAD	F
Methylmalonic Acidemia (MMA)			
due to Methylmalonyl-CoA Mutase Deficiency	**251000**	MUT	O
Cobalamin A (CblA) or Cobalamin B (CblB) deficiency	**277400**	Cbl A,B	
Methylmalonic Acidemia with Homocystinuria (Cbl C or D type)	**251100**	Cbl, C,D	
Multiple CoA Carboxylase Deficiency	**253270**	MCD	O
Nonketotic Hyperglycinemia			
due to Glycine Cleavage System H Protein Deficiency	**238330**	NKH	AA
due to Aminomethyltransferase Deficiency	**238310**		
due to Glycine Decarboxylase Deficiency	**238300**		
Ornithine Transcarbamylase Deficiency	**311250**	OTC	AA
Phenylketonuria	**261600**	PKU	AA
Propionic Acidemia	**606054**	PROP	O
Short Chain AcylCoA Dehydrogenase Deficiency	**606885**	SCAD	F
Trifunctional Protein Deficiency	**609015**	TFP	F
Tyrosinemia			
Type I	**276700**	TYR I	AA
Type II	**276600**	TYR II	
Type III	**276710**	TYR III	
Very Long Chain AcylCoA Dehydrogenase Deficiency	**201475**	VLCAD	F
X-linked Adrenoleukodystrophy	**300100**	ABCD1	F

NEWBORN SCREENING DISORDERS

AA (Amino Acid)/ E (Endocrine)/ F (Fatty)/ Hb (Hemoglobin)/ O (Organic)

Disorders by Other Methods	OMIM	Code	
Biotinidase Deficiency	**609019**	BIOT	--
Congenital Adrenal Hyperplasia	**201910**	CAH	E
Congenital Hypothyroidism	**218700** **275200**	CH	E
Critical Congenital Heart Disease		CCHD	--
Cystic Fibrosis	**219700**	CF	--
Galactosemia Galt Deficiency Galactokinase Deficiency Epimerase Deficiency	 **230400** **230200** **230350**	 GALT GALK GALE	--
Hearing Loss		HEAR	--
Hemoglobinopathies (HGB) Sickle cell anemia Sickle Beta Thalassemia SC Disease Various other Hgb Disesase	**603903**	 Hb SS Hb S/βTh Hb S/C Var Hb	Hb
Severe Combined Immunodeficiency Other T-Cell related lymphocyte deficiencies	**300400**	SCID	--

MILITARY TIME CONVERSION CHART

Civilian Time	Military Time
1:00 AM	01:00
2:00 AM	02:00
3:00 AM	03:00
4:00 AM	04:00
5:00 AM	05:00
6:00 AM	06:00
7:00 AM	07:00
8:00 AM	08:00
9:00 AM	09:00
10:00 AM	10:00
11:00 AM	11:00
12:00 PM	12:00
1:00 PM	13:00
2:00 PM	14:00
3:00 PM	15:00
4:00 PM	16:00
5:00 PM	17:00
6:00 PM	18:00
7:00 PM	19:00
8:00 PM	20:00
9:00 PM	21:00
10:00 PM	22:00
11:00 PM	23:00
12:00 AM	24:00

An infant born at 12:05 AM or 5 minutes after midnight would be written as 0005 military time.

POUNDS AND OUNCES TO GRAMS CONVERSION CHART

To obtain grams equivalent to 5 pounds, 8 ounces, read “5” on top scale and “8” on side scale; equivalent is 2495 grams.

	POUNDS															
oz.	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
0	0	454	907	1361	1814	2268	2722	3175	3629	4082	4536	4990	5443	5897	6350
1	28	482	936	1389	1843	2296	2750	3203	2657	4111	4564	5018	5471	5925	6379
2	57	510	963	1417	1871	2325	2778	3232	3686	4139	4593	5046	5500	5953	6407
3	85	539	992	1446	1899	2353	2807	3260	3714	4167	4621	5075	5528	5982	6435
4	113	567	1021	1474	1928	2381	2835	3289	3742	4196	4649	5103	5557	6010	6464
5	142	595	1049	1503	1956	2410	2863	3317	3770	4224	4678	5131	5585	6038	6495
6	170	624	1077	1531	1984	2438	2892	3345	3799	4252	4706	5160	5613	6067	6520
7	198	652	1106	1559	2013	2466	2920	3374	3827	4281	4734	5188	5642	6095	6549
8	227	680	1134	1588	2041	2495	2948	3402	3856	4309	4763	5216	5670	6123	6577
9	255	709	1162	1616	2070	2523	2977	3430	3884	4337	4791	5245	5698	6152	6605
10	383	737	1191	1644	2098	2551	3005	3459	3912	4366	4819	5273	5727	6180	6634
11	312	765	1219	1673	2126	2580	3033	3487	3941	4394	4848	5301	5755	6209	6662
12	340	793	1247	1701	2155	2608	3062	3515	3969	4423	4876	5330	5783	6237	6690
13	369	822	1276	1729	2183	2637	3090	3544	3997	4451	4904	5358	5812	6265	6719
14	397	850	1304	1758	2211	2665	3118	3572	4026	4479	4933	5386	5840	6294	6747
15	425	879	1332	1786	2240	2693	3147	3600	4054	4508	4961	5415	5868	6322	6776

1000 grams = 1 kilogram

1 pound = 453.59237 grams

1 ounce = 28.349523 grams

**Gram equivalents have been rounded to whole numbers by adding one when the first decimal place in 5 or greater.

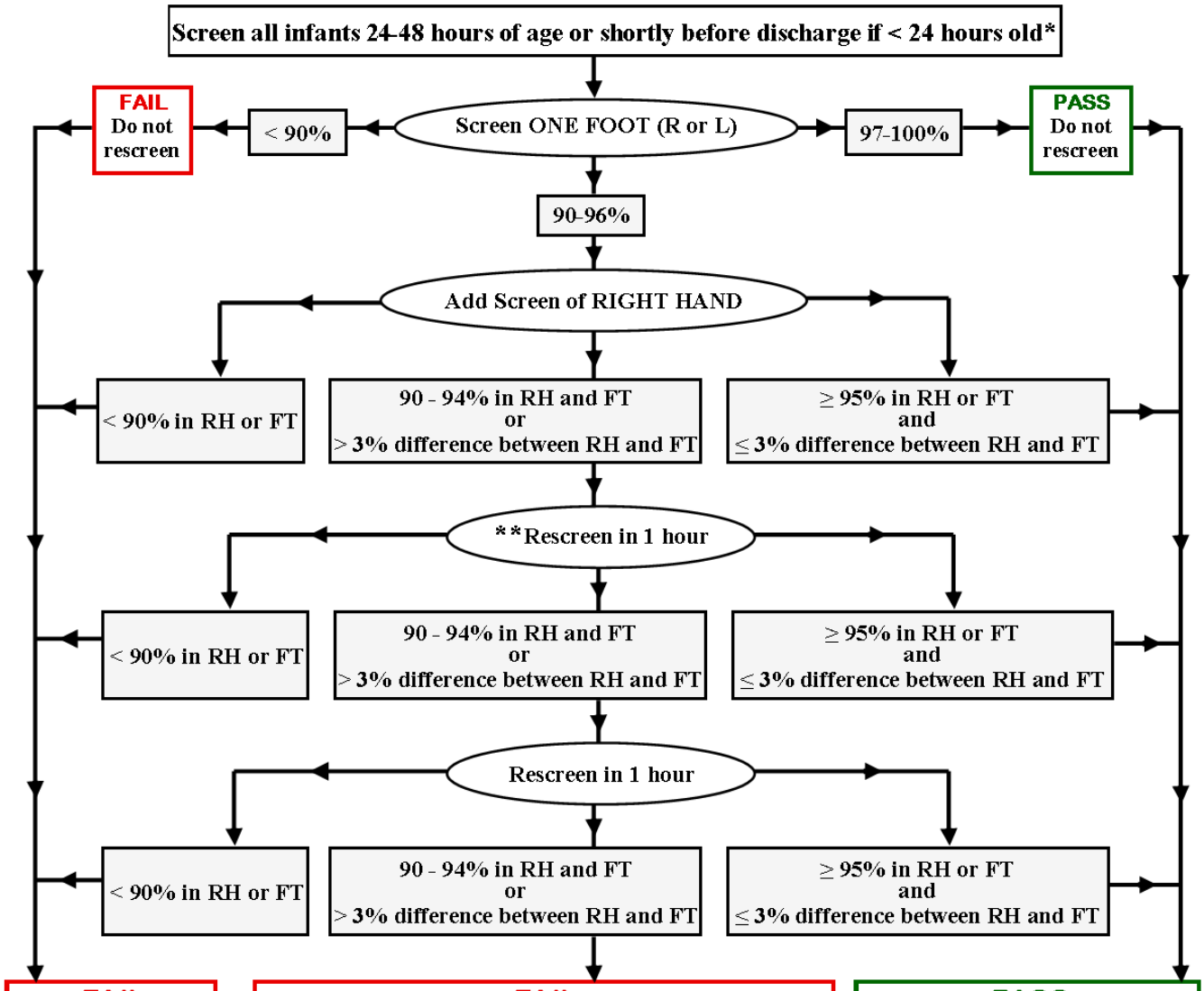
TENNESSEE COUNTY CODE LIST

County Code	County Name	County Code	County Name	County Code	County Name
1	ANDERSON	33	HAMILTON	65	MORGAN
2	BEDFORD	34	HANCOCK	66	OBION
3	BENTON	35	HARDEMAN	67	OVERTON
4	BLEDSOE	36	HARDIN	68	PERRY
5	BLOUNT	37	HAWKINS	69	PICKETT
6	BRADLEY	38	HAYWOOD	70	POLK
7	CAMPBELL	39	HENDERSON	71	PUTNAM
8	CANNON	40	HENRY	72	RHEA
9	CARROL	41	HICKMAN	73	ROAN
10	CARTER	42	HOUSTON	74	ROBERTSON
11	CHEATHAM	43	HUMPHREYS	75	RUTHERFORD
12	CHESTER	44	JACKSON	76	SCOTT
13	CLAIBORNE	45	JEFFERSON	77	SEQUATCHIE
14	CLAY	46	JOHNSON	78	SEVIER
15	COCKE	47	KNOX	79	SHELBY
16	COFFEE	48	LAKE	80	SMITH
17	CROCKETT	49	LAUDERDALE	81	STEWART
18	CUMBERLAND	50	LAWRENCE	82	SULLIVAN
19	DAVIDSON	51	LEWIS	83	SUMNER
20	DECATUR	52	LINCOLN	84	TIPTON
21	DEKALB	53	LOUDON	85	TROUSDALE
22	DICKSON	54	MCMINN	86	UNICOI
23	DYER	55	MCNAIRY	87	UNION
24	FAYETTE	56	MACON	88	VAN BUREN
25	FENTRESS	57	MADISON	89	WARREN
26	FRANKLIN	58	MARION	90	WASHINGTON
27	GIBSON	59	MARSHALL	91	WAYNE
28	GILES	60	MAURY	92	WEAKLY
29	GRAINGER	61	MEIGS	93	WHITE
30	GREENE	62	MONROE	94	WILLIAMSON
31	GRUNDY	63	MONTGOMERY	95	WILSON
32	HAMBLEN	64	MOORE	96	OUT OF STATE

COMMON CAUSES OF UNSATISFACTORY NEWBORN SCREENING SPECIMENS

Unsatisfactory Specimen Conditions	Possible Cause
< 24 hours	Specimen collected before the infant was 24 hours of age
> 10 days	Specimen received greater than 10 days after the date of collection.
> 6 months	Infant greater than 6 months of age at time of collection
Accident	Laboratory Accident
Altered Card	Use of capillary tube or syringe to apply blood can scratch the filter card Rubbing the spot when it is still wet Pressing the heel to the filter card during the collection process
Both Sides	Applying blood to both sides of the filter card
Cells & Serum Separated	The usual cause is squeezing the heel during the specimen collection Waiting too long for the drop of blood to form or by clotted blood Applying blood with a capillary tube device, blood not well-mixed
Clotted Specimen	Improper puncture Application of blood with a capillary tube device Waiting too long for a drop of blood to form
Contaminated	Specimen contaminated with alcohol, water, formula, urine, or hand lotion, etc.
Detached	Blood spot filter paper detached from information portion of the card
Filter Paper Expired	Specimen collected on expired filter paper
Heated	Too long in transit especially during the summer Heating a specimen to dry it **Will appear much darker than usual
Inaccurate Information	Information on form was inaccurate or incorrect (for example: wrong date of birth, date and/or time of collection)
Incomplete Information	All or part of the blanks on the form were not filled out completely (for example: missing date and/or time of collection)
No Blood	Form received with no blood on filter paper
Nonuniform	Applying many small drops of blood to each circle Applying blood with any type of capillary tube Touching the blood drops when they are wet Uneven soaking through the filter card caused by exposure to moisture Glove powder touching filter card area before collection Contaminated surfaces with any of the above contaminants
Poly Bag	Specimen received in a sealed poly bag, plastic zip lock bag, plasticene envelope, or plastic shipping bag
QNSCOM	Quantity not sufficient to complete testing (Some tests could not be completed due to insufficient blood)
Quantity Not Sufficient (QNS)	The drops of blood are too small Improper use of lancet or dropping blood from a capillary tube device
Supersaturated	The drops of blood are too large The drops of blood overlap or touch one another The filter card is pressed against the puncture site The blood is dropped in very large drops from a capillary tube

PROTOCOL FOR CRITICAL CONGENITAL HEART DISEASE SCREENING



FAIL

- SpO2 <90% in either the hand or foot at anytime during screening should have immediate clinical assessment by primary care providers.
- Do not rescreen in one hour.

FAIL

- There is a 20% chance the infant has a CCHD. Notify medical practitioner of the failed screen and need for further evaluation.
- Primary care providers should evaluate for causes of ↓ oxygen saturation (e.g., persistent pulmonary hypertension, pneumonia, infection, etc).
- In the absence of a clear cause of hypoxemia, obtain a diagnostic echocardiogram by an expert in the interpretation of infant echocardiograms. The report should be reviewed and appropriate action taken prior to discharge home. This may require transfer to another institution or use of telemedicine.

PASS

Do not rescreen

- Pass <u>does not exclude</u> the existence of a cardiac disorder.
- If cardiac evaluation is otherwise indicated (e.g., clinical signs, prenatal diagnosis of critical congenital heart disease, dysmorphic features, etc.), proceed with cardiac evaluation even if infant receives a pass on the pulse oximetry screen.

- Optimal results are obtained by pulse oximeter that has been cleared by FDA for use in newborn.
- This screening algorithm should not take the place of clinical judgment or customary clinical practice.

RH = Right Hand FT = Foot Sp02 = Saturation of Peripheral Oxygen

*Infants in special care nurseries (including intermediate care and neonatal intensive care, etc.) should be screened at 24-48 hours of age or when medically appropriate after 24 hours of age. In all cases, screening should occur prior to discharge from the hospital.

**If screen with RH and FT shows 90 - 94% or there is >3% difference between RH and FT and the infant is <24 hours of age, rescreen from start of algorithm after the infant is 24-48 hours of age. If infant is >24 hours of age, rescreen in 1 hour.

Chart for identifying infants with > 3% difference between the right hand and foot:

RIGHT HAND \ FOOT	100	99	98	97	96	95	94	93	92	91	90	<90
100	100	99	98	97	96	95	94	93	92	91	90	<90
99	100	99	98	97	96	95	94	93	92	91	90	<90
98	100	99	98	97	96	95	94	93	92	91	90	<90
97	100	99	98	97	96	95	94	93	92	91	90	<90
96	100	99	98	97	96	95	94	93	92	91	90	<90
95	100	99	98	97	96	95	94	93	92	91	90	<90

Right hand screening not needed if foot saturation is 97-100%

TENNESSEE BIRTHING FACILITY CODE LIST

Provider ID	Facility Name	Provider ID	Facility Name
0109520	METHODIST MEDICAL CTR OF OAK RIDGE	2706524	GIBSON GENERAL HOSPITAL
0509020	BLOUNT MEMORIAL HOSPITAL	2707225	HUMBOLDT GENERAL HOSPITAL
0607922	TENNOVA HEALTHCARE-CLEVELAND	2805221	HILLSIDE HOSPITAL
0710625	JELLICO COMMUNITY HOSPITAL	3008422	LAUGHLIN MEMORIAL HOSPITAL
0800021	STONES RIVER HOSPITAL - TRI STAR	3008423	TAKOMA ADVENTIST HOSPITAL
0901324	BAPTIST MEMORIAL HUNTINGDON	3209224	MORRISTOWN-HAMBLEN HOSPITAL
0904225	MCKENZIE REGIONAL HOSPITAL	3209225	LAKEWAY REGIONAL HOSPITAL
1008322	SYCAMORE SHOALS HOSPITAL	3307720	TCTCH
1504922	NEWPORT MEDICAL CENTER	3307723	ERLANGER EAST HOSPITAL
1604421	COFFEE MEDICAL CENTER	3308239	PARKRIDGE EAST HOSPITAL
1604424	MEDICAL CENTER OF MANCHESTER	3400020	HANCOCK COUNTY HOSPITAL
1609823	TENNOVA HEALTHCARE - HARTON	3501621	BOLIVAR COMMUNITY HOSPITAL INC
1802222	CUMBERLAND MEDICAL CENTER	3605620	HARDIN MEDICAL CENTER
1909255	EAST END WOMEN'S HEALTH & BIRTH CTR	3705522	HAWKINS COUNTY MEMORIAL HOSPITAL
19094001	BABY+ CO NASHVILLE	3801722	METHODIST HEALTHCARE-BROWNSVILLE
1909421	SOUTHERN HILLS MEDICAL CTR	3903921	HENDERSON COUNTY COMMUNITY HOSPITAL
1909422	MEHARRY HUBBARD HOSPITAL	4005122	HENRY COUNTY MEDICAL CENTER
1909424	METRO-NASHVILLE GENERAL HOSPITAL	4100621	ST THOMAS HICKMAN HOSPITAL
1909425	ST THOMAS MIDTOWN - NASHVILLE	4200020	TRINITY HOSPITAL
1909428	VANDERBILT NICU	4306720	THREE RIVERS COMMUNITY HOSPITAL
1909429	VANDERBILT HOSPITAL -WELL BABY	4503424	JEFFERSON MEMORIAL HOSPITAL
1909433	SKYLINE MEDICAL CENTER	4700028	UNIVERSITY OF TENN MEDICAL CTR
1909434	SUMMIT MEDICAL CENTER	4708821	FORT SANDERS REGIONAL MEDICAL CTR
1909435	CENTENNIAL MEDICAL CTR	4708824	PHYSICIANS REGIONAL MEDICAL CENTER
2000020	DECATUR COUNTY GENERAL HOSPITAL	4708829	EAST TENN CHILDRENS HOSPITAL
2106623	BAPTIST DEKALB HOSPITAL	47088259	BABY+ CO KNOXVILLE
2202420	HORIZON MEDICAL CENTER	4708832	PARKWEST MEDICAL CENTER
2308121	DYERSBURG REGIONAL MEDICAL CTR	4788249	TURKEY CREEK MEDICAL CENTER
2400022	METHODIST HOSPITAL OF FAYETTE	5003623	SOUTHERN TN MEDICAL CTR - LAWRENCEBURG
2500020	JAMESTOWN REGIONAL MEDICAL CTR	5100010	THE FARM
2606822	SOUTHERN TN MEDICAL CTR- WINCHESTER	5101220	LEWIS COMMUNITY HOSPITAL
2704620	CITY OF MILAN HOSPITAL	5202721	LINCOLN MEDICAL CENTER

Please be sure to enter the code that indicates the location of the infant's birth ***and*** the collection hospital.

TENNESSEE BIRTHING FACILITY CODE LIST

Provider ID	Facility Name	Provider ID	Facility Name
5304120	FORT SANDERS LOUDON MEDICAL CTR	7909124	REGIONAL MEDICAL CTR AT MEMPHIS
5402623	WOODS MEMORIAL HOSPITAL	7909127	METHODIST HEALTHCARE UNIV HOSP -MEM
5407524	ATHENS REGIONAL MEDICAL CENTER	7909130	LE BONHEUR CHILDRENS MEDICAL CTR
5505022	TENNOVA HEALTHCARE - MCNAIRY	7909131	METHODIST HOSPITAL-GERMANTOWN
5708524	JACKSON MADISON COUNTY GEN HOSP	7909134	METHODIST HOSPITAL-NORTH
5708526	TENNOVA HEALTHCARE - REGIONAL JACKSON	7909136	METHODIST HOSPITAL-SOUTH
5800022	WHITWELL MEDICAL CENTER	7909139	ST FRANCIS HOSPITAL-MEMPHIS
5806123	GRANDVIEW MEDICAL CENTER	7909140	BAPTIST MEMORIAL HOSP FOR WOMEN
5903824	MARSHALL MEDICAL CENTER	7909161	ST FRANCIS HOSPITAL-BARTLETT
6008022	MAURY REGIONAL HOSPITAL	7909239	BAPTIST MEMORIAL HOSPITAL-COLLIERVILLE
6200050	WOMEN'S WELLNESS & MATERNITY CTR	8000021	CARTHAGE GENERAL HOSPITAL INC
6206420	SWEETWATER HOSPITAL ASSOCIATION	8000254	ALMOST HOME BIRTHING CENTER
6300070	BLANCHFIELD ARMY COMMUNITY HOSPITAL	8000420	RIVERVIEW REGIONAL MEDICAL CTR - NORTH
6307820	TENNOVA HEALTHCARE - CLARKSVILLE	8207620	BRISTOL REGIONAL MEDICAL CENTER
6609920	BAPTIST MEMORIAL HOSP UNION CITY	8208721	HOLSTON VALLEY MEDICAL CENTER
6704021	LIVINGSTON REGIONAL HOSPITAL	8208725	INDIAN PATH MEDICAL CENTER
6800020	PERRY MEMORIAL HOSPITAL	8300000	THE TENNESSEE BIRTHPLACE
7000022	COPPER BASIN MEDICAL CENTER	8304720	TN CHRISTIAN MEDICAL CNTR-PORTLAND
7107020	COOKEVILLE REGIONAL MEDICAL CENTER	8307124	SUMNER REGIONAL MEDICAL CENTER
71070257	INFINITY BIRTHING CTR	8310425	HENDERSONVILLE MEDICAL CENTER
7202322	RHEA COUNTY MEDICAL CENTER	8402125	BAPTIST MEMORIAL HOSPITAL TIPTON
7303121	HARRIMAN CITY HOSPITAL	8907323	RIVER PARK HOSPITAL
7305420	BAPTIST HOSPITAL OF ROANE CO	9008625	FRANKLIN WOODS COMMUNITY HOSPITAL
7406321	NORTHCREST MEDICAL CENTER	9008628	JOHNSON CITY MED CENTER-WBN
7509321	ST THOMAS RUTHERFORD HOSPITAL	9008629	JOHNSON CITY MED CENTER-NICU
7559501	STONE CREST MEDICAL CTR	9100000	NATCHEZ TRACE MATERNITY CTR
7604321	SCOTT COUNTY HOSPITAL	9100021	WAYNE MEDICAL CENTER
7700521	NORTH VALLEY MEDICAL PLAZA	9204522	TENNOVA HEALTHCARE - MARTIN
7800023	LECONTE MEDICAL CENTER	9306220	WHITE CO COMMUNITY HOSPITAL
7909127	METHODIST HEALTHCARE UNIV HOSPITAL-MEM	9402823	WILLIAMSON MEDICAL CENTER
7909130	LE BONHEUR CHILDRENS MEDICAL CTR	9508922	TENNOVA HEALTHCARE - LEBANON
7900073	NAVAL REGIONAL MEDICAL CENTER		

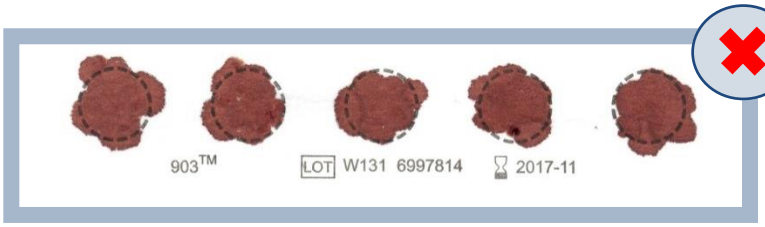
Please be sure to enter the code that indicates the location of the infant's birth *and* the collection hospital.

NEWBORN SCREENING UNSATISFACTORY SPECIMEN IDENTIFICATION GUIDE

TN Department of Health

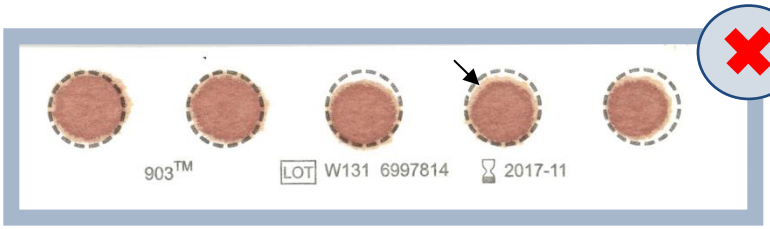
A Satisfactory Specimen Has:

- No contaminations on the filter paper
- All printed circles completely filled with blood that is applied evenly on one side of the filter paper
- No of layering and clots; is soaked through evenly
- Dried for 3 hours on a horizontally level, non-absorbent, open surface



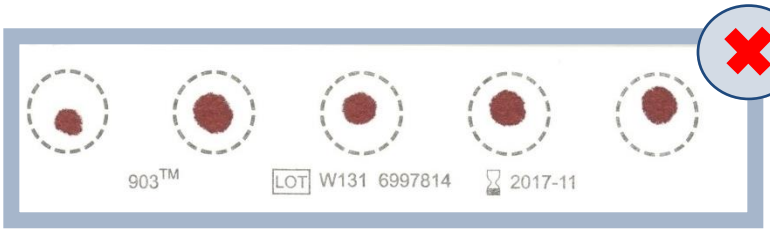
Non Uniform:

- Apply a large, single drop of blood to fill the circle
- Avoid application of blood with a capillary tube/syringe
- Do not touch the blood drops when they are wet



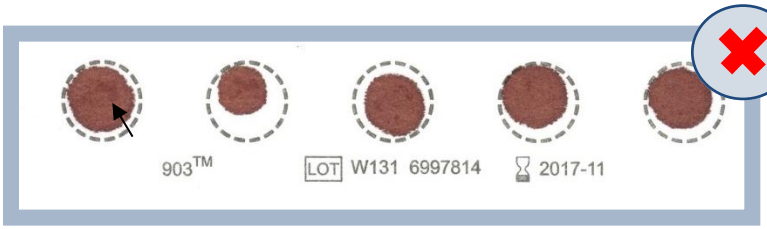
Cells & Serum Separated:

- Rapidly apply the drop of blood onto the card
- Make sure the puncture site is dry after wiping with alcohol
- Avoid excessive squeezing at the puncture site
- Do not use a capillary tube/syringe



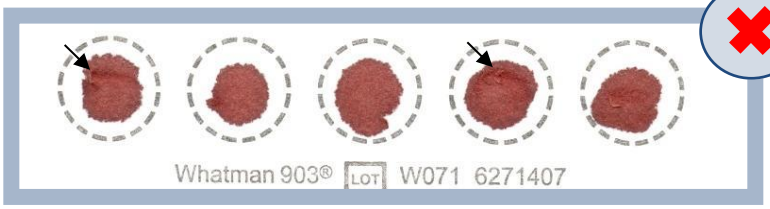
Quantity Not Sufficient:

- The drops of blood are too small
- Allow a large drop of blood to form before allowing it to touch the card
- Proper lancet use during collection
- Do not use blood from a capillary tube/syringe



Blood Clotted:

- Ensure proper puncture methods
- Allow a large drop of blood to form before allowing it to touch the card
- Do not use a capillary tube to distribute blood drops



Avoid Altered Paper:

- Do not use a capillary tube/syringe to apply blood to the filter card
- Avoid contact with the blood spot while it is wet
- Keep the infant's heel from pressing card during collection
- Store filter cards on their side in a cool, clean, and dry place

Tennessee Newborn Screening Program

NEWBORN SCREENING UNSATISFACTORY SPECIMEN IDENTIFICATION GUIDE

TN Department of Health

Blood on Both Sides of Filter Paper Cards:

- Can be avoided by only applying blood to one side of the card
- Blood can be applied to either side of the filter paper. Collection should be on only one side of the filter paper; not both.

Contaminated Specimen:

- Do not touch the blood drops when they are wet
- Wear powder free gloves during collection
- Avoid use of hand creams or lotions
- Make sure the puncture site is dry after wiping with alcohol

Incomplete Information on Specimen:

- Occurs when the information on the card is not completed
- Examples are: date of birth, time of birth, transfusion date, etc.
- To avoid this, be sure to complete all areas of the form legibly and accurately

Poly Bag Mailing:

- Specimens received in a sealed poly bag, plastic zip lock bag, plastic envelope or shipping bag
- Do not use any type of plastic bag or material for mailing the specimen
- *Only use paper envelopes for mailing*

Supersaturated:

- The drops of blood are too large and overlap or touch one another
- Can occur if the filter card is pressed against the puncture site or the blood is dropped in very large drops from a capillary tube
- To avoid this, do not drop blood drops on top of each other, let blood spots touch, or use a capillary tube to distribute blood drops

>10 Days:

- Specimen was received in the laboratory greater than 10 days after the date of collection
- Use the proper transit method to ensure prompt delivery of specimens
- Mail specimens using the provided courier service within 24 hours of collection

Inaccurate Information on Specimen:

- Information on the collection form is not correct
- This can be avoided by using caution when completing the cards and checking all information for accuracy.

Heated Filter Paper Cards:

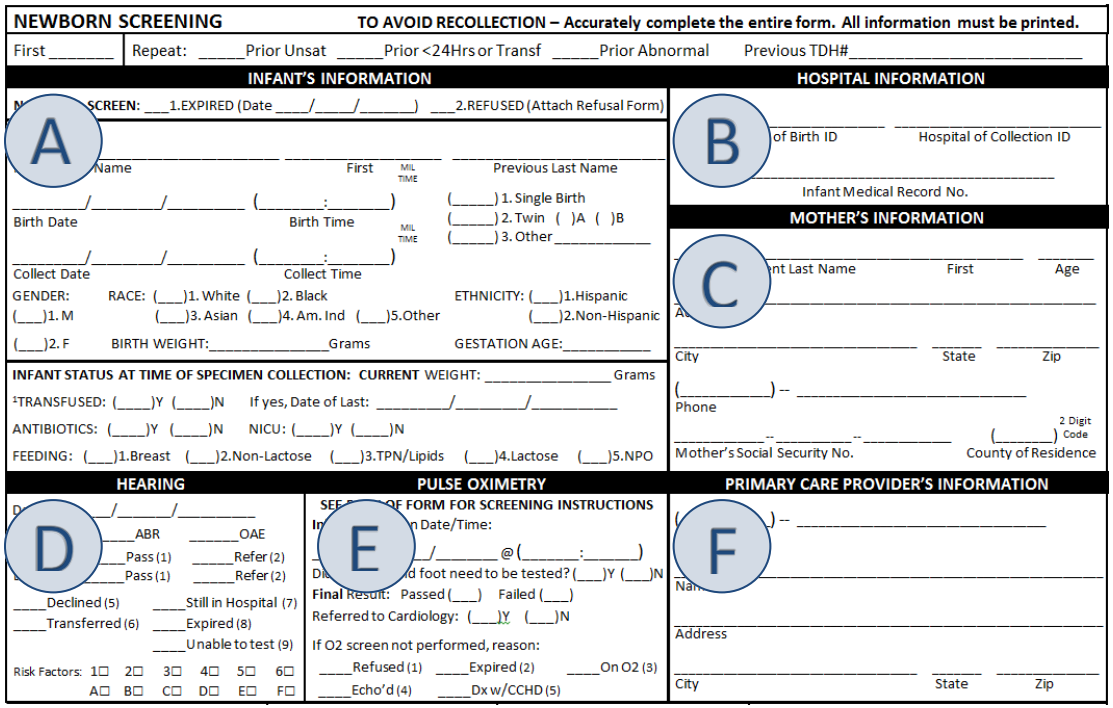
- Can be caused by use of heat as a drying method, long transit times, and/or humidity
- *Do not use heat to dry specimens*
- Be sure to allow specimens to dry for at least 3 hours

Newborn Screening Program Contact Information

Follow-Up: 615-532-8462
nbs.health@tn.gov
Laboratory: 615-262-6300
LabNBS.Health@tn.gov

Tennessee Newborn Screening Program

The Newborn Screening Collection Form



NEWBORN SCREENING — TO AVOID RECOLLECTION – Accurately complete the entire form. All information must be printed.

First _____ | Repeat: _____Prior Unsat _____Prior <24Hrs or Transf _____Prior Abnormal Previous TDH#_____

INFANT'S INFORMATION

SCREEN: ___1.EXPIRED (Date ____/____/_____) ___2.REFUSED (Attach Refusal Form)

A

Name First MIL TIME Previous Last Name

_____/_____/_____ (_____:_____) (_____) 1. Single Birth

Birth Date Birth Time (_____) 2. Twin ( )A ( )B

MIL TIME (_____) 3. Other _____

_____/_____/_____ (_____:_____)

Collect Date Collect Time

GENDER: (___)1. M (___)2. F

RACE: (___)1. White (___)2. Black (___)3. Asian (___)4. Am. Ind (___)5.Other

ETHNICITY: (___)1.Hispanic (___)2.Non-Hispanic

BIRTH WEIGHT:_____Grams GESTATION AGE:_____

INFANT STATUS AT TIME OF SPECIMEN COLLECTION: CURRENT WEIGHT: _____ Grams

¹TRANSFUSED: (____)Y (____)N If yes, Date of Last: _____/_____/_____

ANTIBIOTICS: (____)Y (____)N NICU: (____)Y (____)N

FEEDING: (___)1.Breast (___)2.Non-Lactose (___)3.TPN/Lipids (___)4.Lactose (___)5.NPO

HOSPITAL INFORMATION

B

_____ _____

of Birth ID Hospital of Collection ID

_____

Infant Medical Record No.

MOTHER'S INFORMATION

C

_____ _____ _____

nt Last Name First Age

_____

A

_____ _____ _____

City State Zip

(_____) -- _____

Phone

_____ -- _____ -- _____ (_____) 2 Digit Code

Mother's Social Security No. County of Residence

HEARING

D

D _____/_____/_____

_____ABR _____OAE

_____Pass (1) _____Refer (2)

_____Pass (1) _____Refer (2)

_____Declined (5) _____Still in Hospital (7)

_____Transferred (6) _____Expired (8)

_____Unable to test (9)

Risk Factors: 1☐ 2☐ 3☐ 4☐ 5☐ 6☐

A☐ B☐ C☐ D☐ E☐ F☐

PULSE OXIMETRY

E

SEE OF FORM FOR SCREENING INSTRUCTIONS

In n Date/Time:

_____/_____/_____ @ (_____:_____)

Di d foot need to be tested? (___)Y (___)N

Final Result: Passed (___) Failed (___)

Referred to Cardiology: (___)Y (___)N

If O2 screen not performed, reason:

_____Refused (1) _____Expired (2) _____On O2 (3)

_____Echo'd (4) _____Dx w/CCHD (5)

PRIMARY CARE PROVIDER'S INFORMATION

F

( ) -- _____

Na

_____

Address

_____ _____ _____

City State Zip

Always fill out the collection form
COMPLETELY, LEGIBLY, and **ACCURATELY!**

A. Inclusion of **birth date, time and weight, collection date and time, gestational age, current weight, transfusion date, antibiotics given, and feeding status** are all vital for

B. For reporting purposes, **the hospital of birth and hospital of collection should ALWAYS be included** considering that they may differ.

C. **Correct demographics are needed in the mother's information section** because it is used to identify infants with like names when reporting results to a PCP or abnormal results to the

D. If results are indicated, **ensure that the screening method is also specified**. If the infant is awaiting a RESCREEN, tear out the pink form, submit dried blood spot screen, and report when results are available.

E. **Only specify if the infant was referred to a cardiologist after clinical assessment (echocardiogram).**

F. **PCP information is important for reporting purposes**. If there is an abnormal result the PCP will be contacted regarding the collection of a repeat specimen.

Newborn Screening DBS Specimen Collection Roadmap

Newborn Screening

Specimen Collection Materials

- Newborn Screening card
- Powder-free gloves
- Alcohol wipes
- Lancet
- Sterile gauze

Process

- Warm baby's foot
- Clean puncture site
- Puncture foot
- Wipe away first drop of blood
- Fill all five circles on collection card

Specimen Card

Include the following key information:

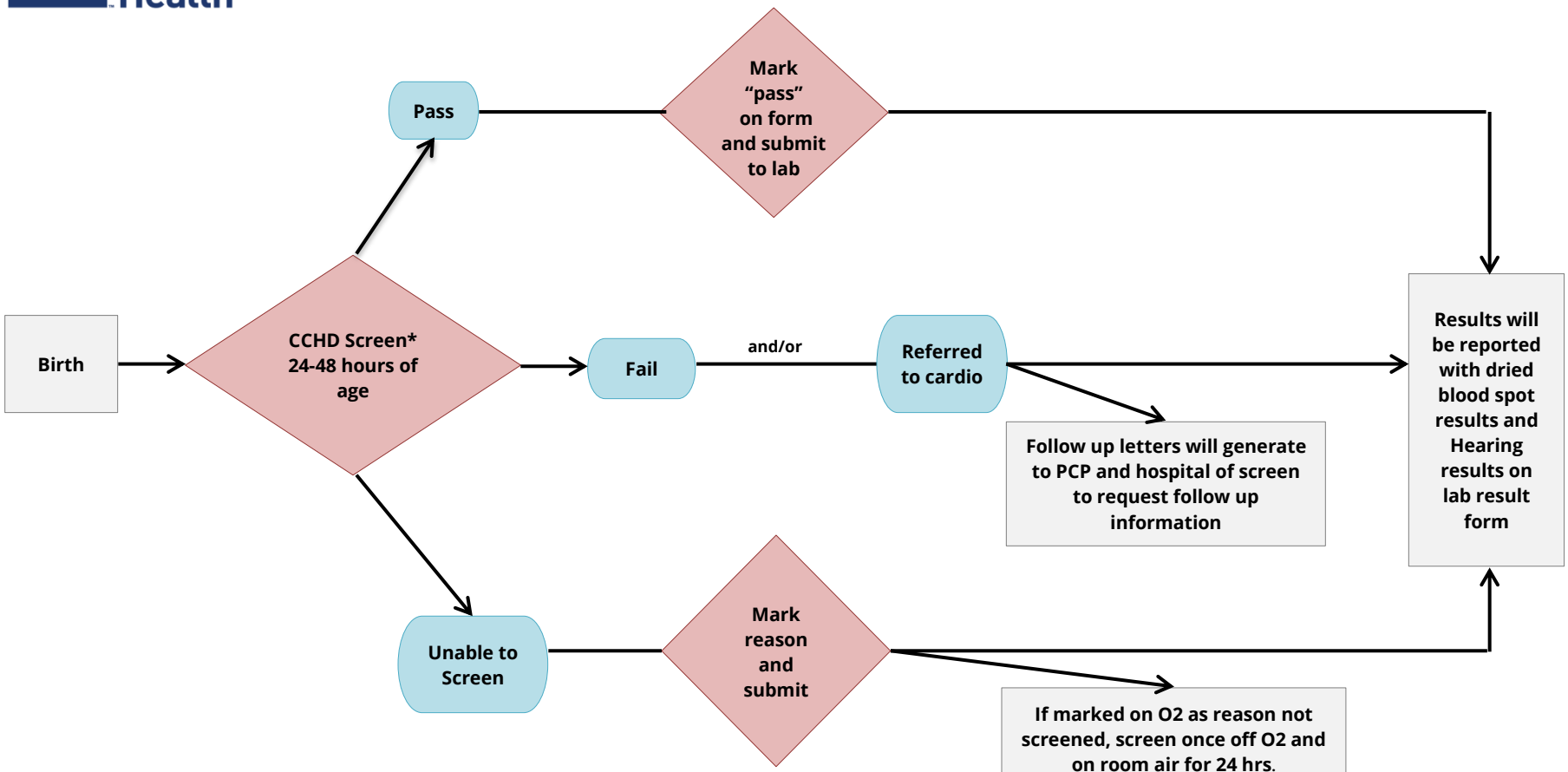
Birth date and time
Collection date and time
Birth and current weights
Gestational age
Mother's Name
Baby's Primary Care Provider
Hospital information

Newborn Screening Program Contact Information

Follow-Up: 615-532-8462
nbs.health@tn.gov
Laboratory: 615-262-6300
LabNBS.Health@tn.gov

*Tennessee Rules and Regulations state that collection be done at 24-48 hours after birth, but we encourage collection at 24+1 to ensure timely receipt of the specimen at the lab for testing.

Newborn CCHD Screening Flowchart



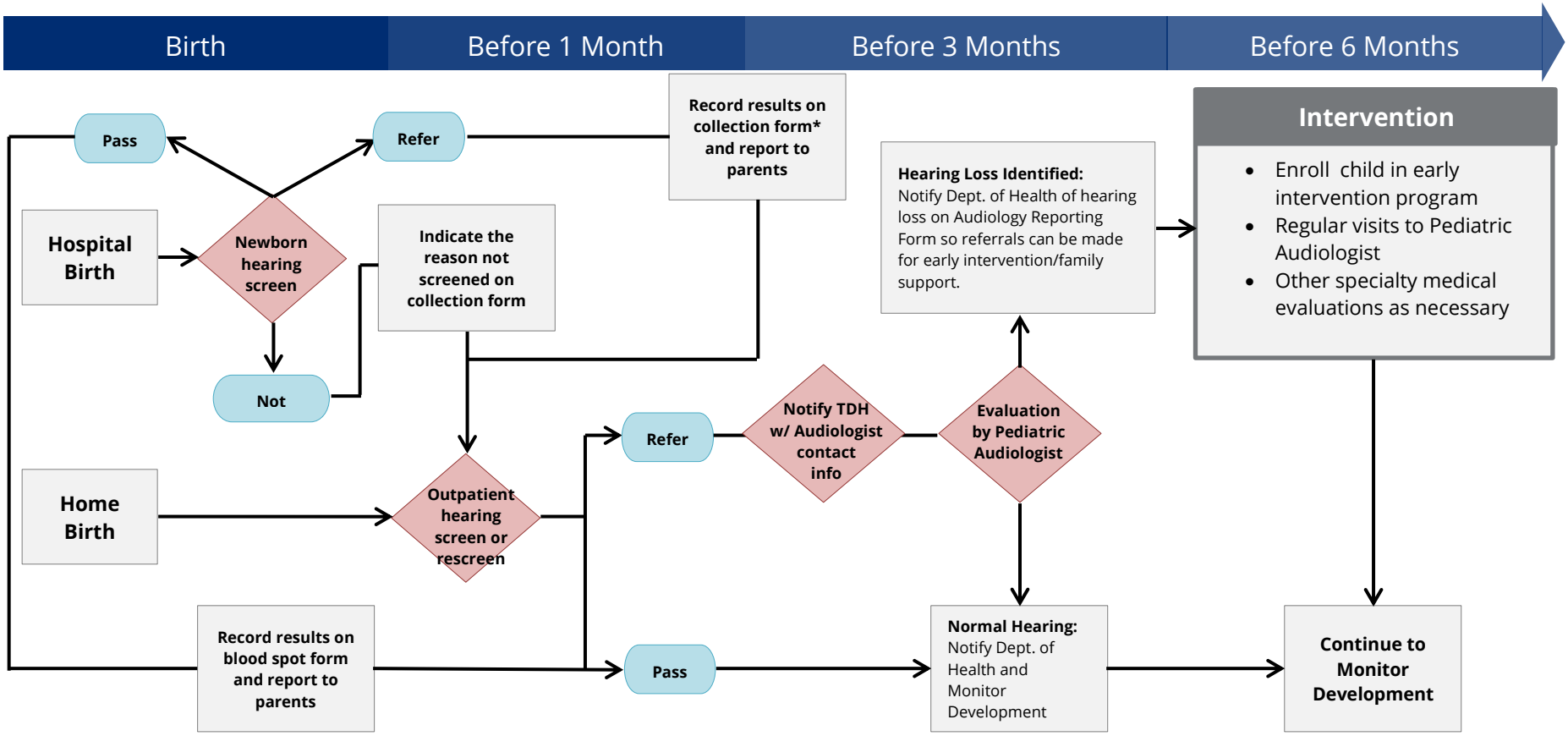
Newborn Screening Program Contact Information

Follow-Up: 615-532-8462
nbs.health@tn.gov
Laboratory: 615-262-6300
LabNBS.Health@tn.gov

Only mark yes in the field "referred to cardiology" if the child was referred to a cardiologist after a failed screen NOT if they only received an ECHO. If a newborn was ECHO'd but did not receive a screen mark reason for not screened as ECHO'd.
CCHD screening is a point of care test so as soon as abnormal results are identified at the time of screening action should be taken immediately.

*The CCHD Screen should be performed using the protocol provided.

Newborn Hearing Screening Roadmap



Newborn Screening Program Contact Information

Follow-Up: 615-532-8462
nbs.health@tn.gov
Laboratory: 615-262-6300
LabNBS.Health@tn.gov

Reporting of CCHD and hearing screen results should **NEVER** delay the submission of a blood card. The pink tear out form may be used to report hearing screen results if the blood spot form is otherwise prepared to be sent to the state lab.

Tennessee Newborn Screening Program

Quality Assurance Processes and Reporting

State of Tennessee Department of Health

Family Health and Wellness
Phone: 615-532-8462 *or* 1-855-202-1357
Fax: 615-532-8555
nbs.health@tn.gov

Laboratory Services
Phone: 615-262-6300
LabNBS.Health@tn.gov

Newborn Screening Quality Assurance Reporting

Pediatric Case Management

The Tennessee Newborn Screening Program is dedicated to ensuring that all babies born in the state receive a newborn screen and that those screens are done correctly and in a timely manner. There are several indicators that are closely monitored to encourage compliance, and each indicator is associated with a goal. The indicators and goals are as follows:

- 100% of infants screened for certain conditions using a dried blood spot (DBS), for critical congenital heart disease (CCHD) using pulse oximetry and for congenital hearing loss via hearing screening.
- <1% for unsatisfactory specimens
- All specimens should be collected between 24-48 hours of age
- All specimens should arrive to the lab <2 days after collection

To ensure that the state goals for these indicators are met, there are various data driven quality improvement activities and reporting measures.

Weekly Reports

Weekly reports are compiled using birth records that are matched to the newborn screening database to identify newborns that have not had a DBS screen. A report is sent to the hospital of birth to review and ensure a DBS has been collected. These reports are intended to assist birthing facilities and the state in meeting the quality indicator of ensuring all infants born in Tennessee are screened for metabolic disorders. See an example of the report on page 4.

Monthly Reports

During the 3rd week of each month, Quality Assurance Summary reports are sent to every collecting facility. The reports include the number and percent of infants with DBS, CCHD and Hearing screens performed, the unsatisfactory rate of DBS specimens submitted, the age at initial DBS collection; and the transit time from DBS collection to arrival at the state laboratory.

If your summary report show infants were not screened, a supplemental detailed report will be included identifying those infants and asking for an update (i.e. results, refusals or deaths) to be sent back to the Newborn Screening Program. The QA Coordinator monitors the responses from the facilities and if screening rates improved. If in one month there is no response or screening rates do not show improvement she will reach out to the facility. ***NOTE: Monthly Quality Assurance Reports should be sent back to the QA Coordinator within five (5) days of receipt.***

If your facility has unsatisfactory specimens submitted, a supplemental detailed report will be included identifying those infants and their reason for being labeled an unsatisfactory specimen. This is a year to date report to assist your facility in identifying issues and addressing them. See examples of the Summary, Detailed Not Screened and Detailed Unsatisfactory reports on pages 4-8.

Quality Improvement Outreach

The QA coordinator uses data compiled from the Monthly Reports to identify hospitals on a monthly basis that do not meet specific performance criteria. Facilities with low screening rates, high unsatisfactory rates, high rates of initial specimen collection >48 hours of age, long transit times; or any combination of these will be contacted on an individual basis to identify the root cause(s) for their low performance.

Trend Monitoring

Reports are compiled to assist in identifying facilities that consistently perform poorly over a period of months. The QA coordinator monitors trends to identify these facilities and reaches out to them to offer assistance or on-site review and training of their internal process to assist in improving timeliness for newborn screening.

Laboratory

In an effort to continually decrease the amount of unsatisfactory specimens that are received at the laboratory, the Newborn Screening manager reviews the distribution of unsatisfactory specimens quarterly. Hospitals with an unsatisfactory rate of >10% receive notification that highlights the following information:

- Unsatisfactory rate
- Total number of specimens received with the total number of unsatisfactory specimens
- Amount charged due to improper collection
- Predominant unsatisfactory cause and possible causes

Birth File Updated: 12/12/2016

Tennessee Department of Health
Newborn Screening Program
Phone: 615-532-8462 Fax: 615-532-8555
WEEKLY REPORT
Infants by Birthing Hospital with Birth Records who DO NOT have a Dried Blood Specimen Print Date: 12/20/2016

IMMEDIATE ATTENTION

Due to the urgent nature of having a Dried Blood Specimen (DBS) collected, birth records will be matched weekly and newborns identified with a missing DBS will be sent to the hospital of birth. It is important to know that these weekly birth files from vital records have not gone through the data cleaning process so some specimens and birth records may not yet be matched.

Reports are **NOT** required to be sent back to follow-up. It is intended to assist both your hospital and the state in meeting the quality indicator of ensuring all infants born in Tennessee are screened for metabolic disorders. We ask that you review the report to ensure a DBS has been collected.

- If specimen has been recently collected, disregard this notice.
- If the infant was transferred prior to collection, notify transfer hospital to collect DBS.
- If the parents refused screening, fill out the filter card, attach the completed refusal form, mark "refused" at the top of the form and submit it to the state lab.
  - Refusal forms available at: http://health.state.tn.us/MCH/NBS/PDFs/PH-3686.pdf.
- If the infant has died prior to collecting a DBS, fill out the filter card, mark "expired" at the top of the form with the date the infant died and submit it to the state lab.
- Otherwise collect a filter paper and submit it to the state lab.

[redacted]

CHILD'S NAME BIRTHDATE MR# GENDER	MOTHER ADDRESS CITY, STATE, ZIP COUNTY
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Total without a dried blood specimen: 4

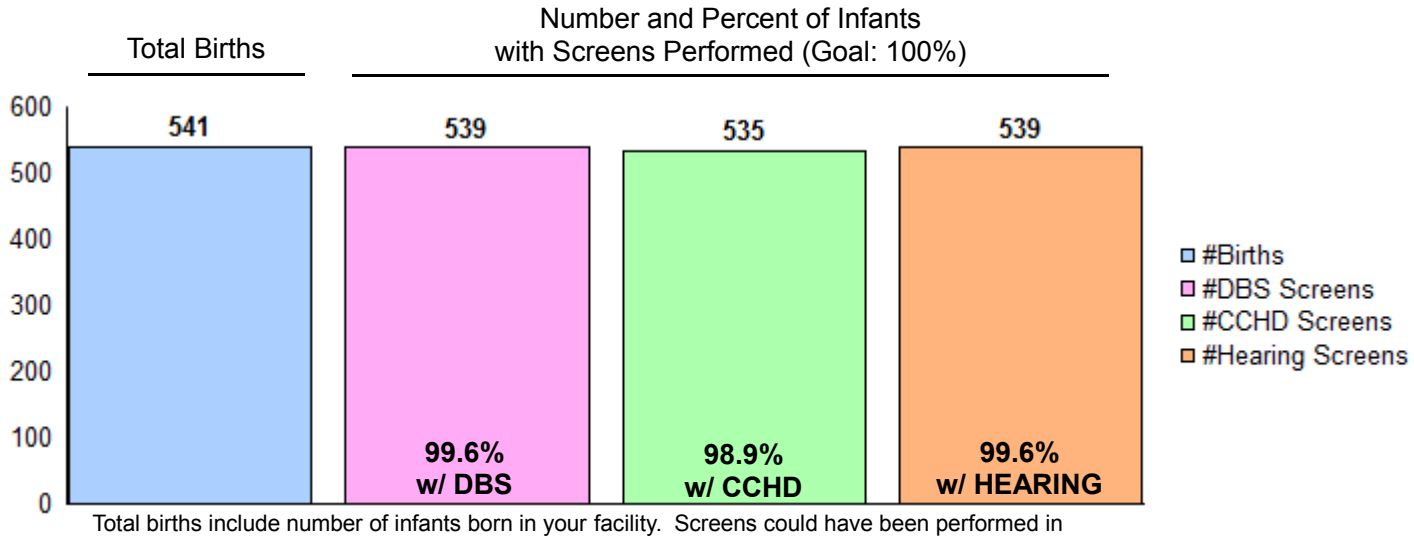
***Numbers cannot be compared to previous reports due to revisions and exclusion changes.**

Report Run: 12/15/2016

Tennessee Newborn Screening Program Hospital Report for [redacted]

Tennessee State Law (TCA 68-5-401) **requires** that all infants born in the State of Tennessee receive screening for certain conditions using a dried blood spot (DBS) screen, for critical congenital heart disease (CCHD) using pulse oximetry and for congenital hearing loss via hearing screening. The Tennessee Newborn Screening Program has prepared the information below to help show your facility's compliance with the law. If an infant was not screened due to refusal, submit the Refusal Form (http://health.state.tn.us/MCH/NBS/PDFs/PH-3686.pdf) by fax to 615-532-8555. Contact us with any questions: 615-532-8462.

Screens Performed for Date of BIRTH Range: 10/1/2016 - 10/31/2016



Total births include number of infants born in your facility. Screens could have been performed in another facility.

Unsatisfactory Specimen Rate for Date of RECEIPT Range: 10/1/2016 - 10/31/2016

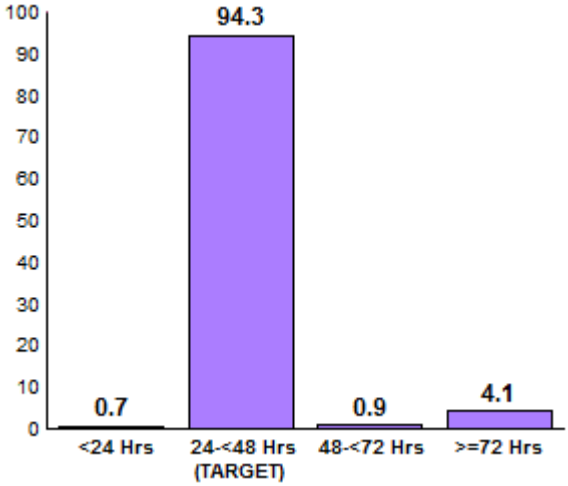
The unsatisfactory specimen rate of the DBS submitted by your facility:

1.74% for your Facility (Goal < 1%)

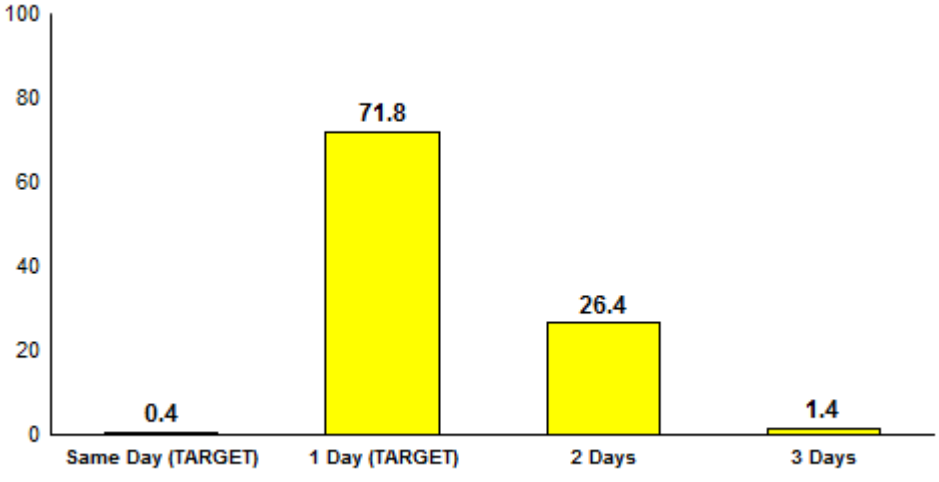
2.89% for all hospitals in the State

Age at Collection and Transit Time Rates for Date of COLLECTION Range: 10/1/2016 - 10/31/2016

Age at Initial DBS Collection (%)
Target: Collected between 24-48 hrs of age*



Transit Time from DBS Collection to State Lab (%)
(Initial and Repeats)
Target: Arrive in lab <2 days from collection*



Age at collection and transit time data are for specimens collected at your facility. For transit time: Same Day means specimen arrived the same day as collection,1 Day means specimen arrived one day after collection, 2 Days means specimen arrived 2 days after collection etc.

***Numbers cannot be compared to previous reports due to revisions and exclusion changes.**

Report Run:3/1/2017

Report Run: 12/15/2016

Tennessee Department of Health Newborn Screening Program
Monthly and Year-to-Date
Unsatisfactory Specimen Hospital Report by Specimen Received Date

[redacted]

	Month: Oct 2016	YTD: Jan-Oct 2016
A: Total specimens submitted	336	2,967
B: Total specimens at < 24 hrs of age	1	6
C: Total specimens reported as transfused	0	0
D: Total specimens excluding <24 hrs and transfused	335	2,961
E: Number of unsatisfactory specimens	4	33
F: % Unsatisfactory for your facility	1.19%	1.11%
G: % Unsatisfactory for State (Goal: <1%)	2.89%	2.25%
>10 days from collection	0	0
Blood clotted	3	15
Blood applied to both sides	0	0
Blood in poly bag	0	6
Cells and serum separated	0	0
Filter paper altered	0	0
Filter paper expired	0	0
Inaccurate information	0	2
Incomplete information	0	2
Insufficient blood to complete	0	0
Nonuniform	1	8
Quantity insufficient	0	0
Specimen appears heated	0	0
Specimen contaminated	0	0
Specimen detached from form	0	0
Supersaturated	0	0
	4	**33**

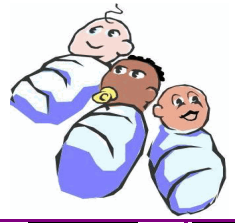
Hospital Detailed Unsatisfactory Specimen Report

Specimen Received: *10/1/2016* To *10/31/2016*

[redacted]

Baby's Name	MR#	Mom's Name	Birth Date	Collect Date	TDH #	SCN #	Unsat Reason
[redacted]							

Total Counts: **4**



Tennessee Department of Health
Newborn Screening Program
Phone: 615-532-8462 Fax: 615-532-8555
Infants by Birthing Hospital with TN Birth Records who DO NOT have a Dried Blood Specimen
Date of Birth Range: 12/1/2016 - 12/31/2016

Report Run: 3/1/2017

[redacted] [redacted]

CHILD'S NAME BIRTHDATE MR# GENDER TDH#	MOTHER ADDRESS CITY, STATE, ZIP COUNTY	NOTES	If screen was collected, provide details below:	If screen was not collected, provide reason:
[redacted]	[redacted]		***Date:*** ____/____/_____ @ ____:____ ***SCN (Form#):*** _____ If dc'd without a specimen, list PCP: Provider: _____ Phone #: _____	☐ *Refused (submit form) ☐ Other/Transfer to: _____ _____ ☐ Died Provide date if NBS did not list it on this report: ____/____/_____
[redacted]	[redacted]	[redacted]	***Date:*** ____/____/_____ @ ____:____ ***SCN (Form#):*** _____ If dc'd without a specimen, list PCP: Provider: _____ Phone #: _____	☐ *Refused (submit form) ☐ Other/Transfer to: _____ _____ ☐ Died Provide date if NBS did not list it on this report: ____/____/_____

Total without a dried blood specimen: 2

Please submit information by fax (615) 532-8555 to the Newborn Screening Program within 5 days of receiving this report. ***I**f parents refused testing please fax the Refusal Form to (615) 532-8555 (http://health.state.tn.us/MCH/NBS/PDFs/PH-3686.pdf).

Tennessee Department of Health
Newborn Screening Program
Phone: 615-532-8462 Fax: 615-532-8555
NO CCHD Screen by Birth Hospital
Date of Birth Range: 12/1/2016 - 12/31/2016

Report Run: 3/1/2017

[redacted] [redacted]

TDH#	CHILD'S NAME BIRTHDATE MR#	MOTHER CITY, STATE, ZIP COUNTY	NOTES	SUBMIT CCHD SCREENING INFORMATION:	If CCHD Screen was still not performed, reason?
[redacted]	[redacted]	[redacted]		Dt/Time:____/____/_____ @____:____ RH & foot? ☐Yes ☐No Result: ☐Passed ☐Failed Cardiology Referral? ☐Yes ☐No	☐On O2 ☐Refused ☐Echo'd ☐Diagnosed with CCHD ☐Died/Date_____ ☐Other/Transfer to: _____
[redacted]	[redacted]	[redacted]	[redacted]	Dt/Time:____/____/_____ @____:____ RH & foot? ☐Yes ☐No Result: ☐Passed ☐Failed Cardiology Referral? ☐Yes ☐No	☐On O2 ☐Refused ☐Echo'd ☐Diagnosed with CCHD ☐Died/Date_____ ☐Other/Transfer to: _____
[redacted]	[redacted]	[redacted]		Dt/Time:____/____/_____ @____:____ RH & foot? ☐Yes ☐No Result: ☐Passed ☐Failed Cardiology Referral? ☐Yes ☐No	☐On O2 ☐Refused ☐Echo'd ☐Diagnosed with CCHD ☐Died/Date_____ ☐Other/Transfer to: _____

Total without CCHD Screen: 3

Please submit information by fax (615) 532-8555 to the Newborn Screening Program within 5 days of receiving this report. CCHD screening fields should not be left blank unless the infant was echo'd, on oxygen when the blood specimen was collected, parents refused testing, the infant died before pulse ox screen was performed or already dx w/CCHD. *If parents refused testing please fax the Refusal Form to (615) 532-8555 (http://health.state.tn.us/MCH/NBS/PDFs/PH-3686.pdf).

Tennessee Department of Health
Newborn Hearing Screening
Phone: 615-532-8462 Fax: 615-532-8555
One Ear or Both Ears *NOT* Screened by Birthing Hospital
Date of Birth Range: 12/1/2016 - 12/31/2016

Report Run: 3/1/2017

[redacted] [redacted]

TDH# / SCN#	CHILD'S NAME / BIRTHDATE / MR#	MOTHER / CITY, STATE	NOTES	Submit Hearing Test Results
[redacted]	[redacted]	[redacted]		Results: ☐ Pass (R) ☐ Refer (R) ☐ Pass (L) ☐ Refer (L) — Date / Method: ____/____/_____ ☐ ABR ☐ OAE — Risk Factors: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F — ☐ Decline ☐ In Hospital ☐ Died ☐ Transfer to_____ ☐ Other:_____

Total without Hearing Screen: 1

Please submit information by fax (615) 532-8555 to the Newborn Screening Program within 5 days of receiving this report.
If parents refused Hearing Screen please fax the refusal form to (615) 532-8555 (http://health.state.tn.us/MCH/NBS/PDFs/PH-3686.pdf).

Risk Factors:

1. NICU > 5 days
2. Syndrome associated with progressive or late onset HL
3. Family history of permanent childhood hearing loss
4. Craniofacial anomalies including those that involve the pinna, ear canal, ear tags, ear pits or temporal bone anomalies
5. In-utero infections such as CMV, Herpes, Rubella, Syphilis, & Toxoplasmosis
6. ECMO

A. Chemotherapy
B. Assisted ventilation
C. Ototoxic medications or loop diuretics
D. Hyperbilirubinemia requiring exchange transfusion
E. Physical findings such as white forelock associated with syndromes known to include SNHL or permanent conductive HL
F. Postnatal culture-positive infections associated with SNHL, including confirmed bacterial and viral (especially Herpes & Varicella), meningitis

TENNESSEE NEWBORN SCREENING PROGRAM
NBS COLLECTION SKILLS CHECKLIST

Employee Name: _____

Preceptor: _____

Unit: _____

Rating Scale

1. Requires assistance and/or practice
2. Competent and can perform independently
3. Competent, performs independently and is able to teach or assess competence of others

Method of Validation

DO – Direct Observation; **V** – Verbal; **S** – Simulation; **O** – Other (please specify)

	Check 1		Check 2		Check 3	
Name of Skill	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**
Collection at 24-48 hours of age or immediately prior to discharge.						
If patient refused blood test, refusal form was completed and sent to TDH.						
Expiration date on filter paper was checked.						
NBS demographics confirmed: Mother's contact information, baby's planned PCP. All required elements filled on form.						
Placed heel warmer on the newborn's heel for 3-5 minutes.						
Performed hand hygiene and wore clean gloves.						
Verified correct patient using hospital/facility protocol.						
Cleaned heel with hospital approved antiseptic. Allowed heel to dry completely after preparing and before lancing.						
Placed infant's leg below heart level to increase venous pressure.						
Performed puncture on outer aspect of infant's heel, and wiped away first drop of blood.						
Applied a single large drop of blood to the center of each circle on the form without allowing the infant's heel to touch the filter paper.						
Observed the saturation of each circle to ensure the blood soaked through the paper.						
Did not oversaturate or under saturate the circles and avoided layering or applying too many small drops of blood per circle.						
Provided comfort to the newborn after the procedure. Discarded supplies, removed gloves, and performed hand hygiene.						
Placed the specimen horizontal on a drying rack for 3-4 hours with no exposure to heat or sunlight. Did not touch the specimen collection area on the filter paper.						
Did not compress the filter paper, close the flap while drying, or stack forms.						
Provided NBS education to parents.						
Had specimen double-checked for satisfactory collection and documentation.						
Specimens packaged for mailing as soon as dry (at least 3 hours). Promptly taken to appropriate area for courier pickup.						

TENNESSEE NEWBORN SCREENING PROGRAM
CCHD SCREENING SKILLS CHECKLIST

Employee Name: _____

Preceptor: _____

Unit: _____

Rating Scale

1. Requires assistance and/or practice
2. Competent and can perform independently
3. Competent, performs independently and is able to teach or assess competence of others

Method of Validation

DO – Direct Observation; **V** – Verbal; **S** – Simulation; **O** – Other (please specify)

	Check 1		Check 2		Check 3	
Name of Skill	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**
Performed at 24-48 hours of age or immediately prior to discharge.						
NBS demographics confirmed: Mother's contact information, baby's planned PCP. All required elements filled on form.						
Performed hand hygiene and wore clean gloves.						
Cleaned infants right hand and either foot prior to testing.						
If using a reusable probe, ensured the probe was disinfected before use.						
Placed the pulse oximeter on the foot that was cleaned following hospital protocol.						
Accurately demonstrated understanding of TN CCHD screening protocol through interpretation of results and any further steps.						
Right hand added to screen if required by protocol.						
Rescreened infant one hour post initial screen as needed.						
Screen results recorded appropriately on the filter paper.						
Results communicated with parents, and parental questions/concerns addressed.						
Educational materials provided to parents.						
Communicated results to medical team.						
Infant referred for further evaluation if results interpreted as FAIL; ***OR***, if clinical symptoms are present.						

Preceptor comments/feedback:

TENNESSEE NEWBORN SCREENING PROGRAM
NEWBORN HEARING SCREENING SKILLS CHECKLIST

Employee Name: _____

Preceptor: _____

Unit: _____

Rating Scale

1. Requires assistance and/or practice
2. Competent and can perform independently
3. Competent, performs independently and is able to teach or assess competence of others

Method of Validation

DO – Direct Observation; **V** – Verbal; **S** – Simulation; **O** – Other (please specify)

	Check 1		Check 2		Check 3	
Name of Skill	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**	**Date & Prec. Initials**	**Rating Scale & Method of Valid**
Performed at 24-48 hours of age or immediately prior to discharge.						
Notified the parents and addressed any questions/concerns presented.						
NBS demographics confirmed: Mother's contact information, baby's planned PCP. All required elements filled on form.						
If refused, completed a refusal form to submit with the filter paper to the State.						
Ensured the baby was calm and in a quiet area before beginning the screening process.						
Visually inspected the infant's ears.						
Performed hand hygiene and wore clean gloves.						
Chose an appropriate probe tip size.						
Placed the probe in the infant's ear correctly and gently.						
Made sure the ear canal was open before beginning.						
Conducted the screen on first ear.						
Ensured that the probe was clean of debris before screening the other ear.						
Properly disposed of probe and other supplies.						
Recorded results and risk factors on the filter paper form.						
Provided the results in writing and verbally to parents.						
If infant had REFER results: made an appointment for re-screen; ***OR***, provided written notice for a re-screen.						
Communicated results to the medical team following hospital protocol.						

Preceptor comments/feedback:

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